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(54) **BLOOD FLOW RESTORATIVE AND EMBOLUS REMOVAL METHODS**

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See application file for complete search history.

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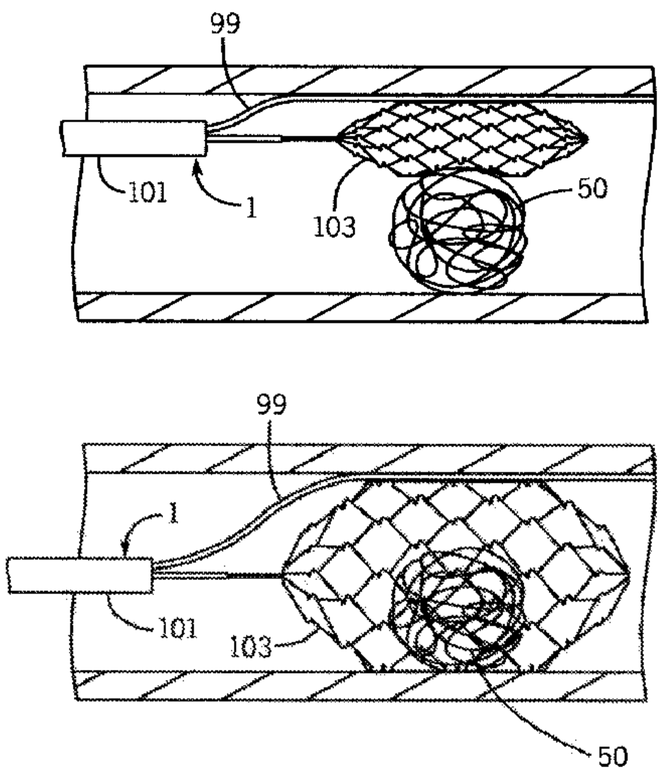
(57) **ABSTRACT**

Methods for restoring blood flow in occluded blood vessels are disclosed. The methods can include accessing an artery with a catheter system and locating an occluded zone within the artery caused by an embolus. The catheter system can include a microcatheter and a blood flow restoration device or an embolus removal device having a self-expandable member configured to be delivered through the microcatheter in a compressed configuration and to be deployed to an expanded configuration upon retraction of the microcatheter. The methods can include deploying the self-expandable member at the location of the occluded zone such that the self-expandable member engages and captures the embolus upon deployment of the self-expandable member and removing the embolus by withdrawing the blood flow restoration device or the embolus removal device.

12 Claims, 51 Drawing Sheets



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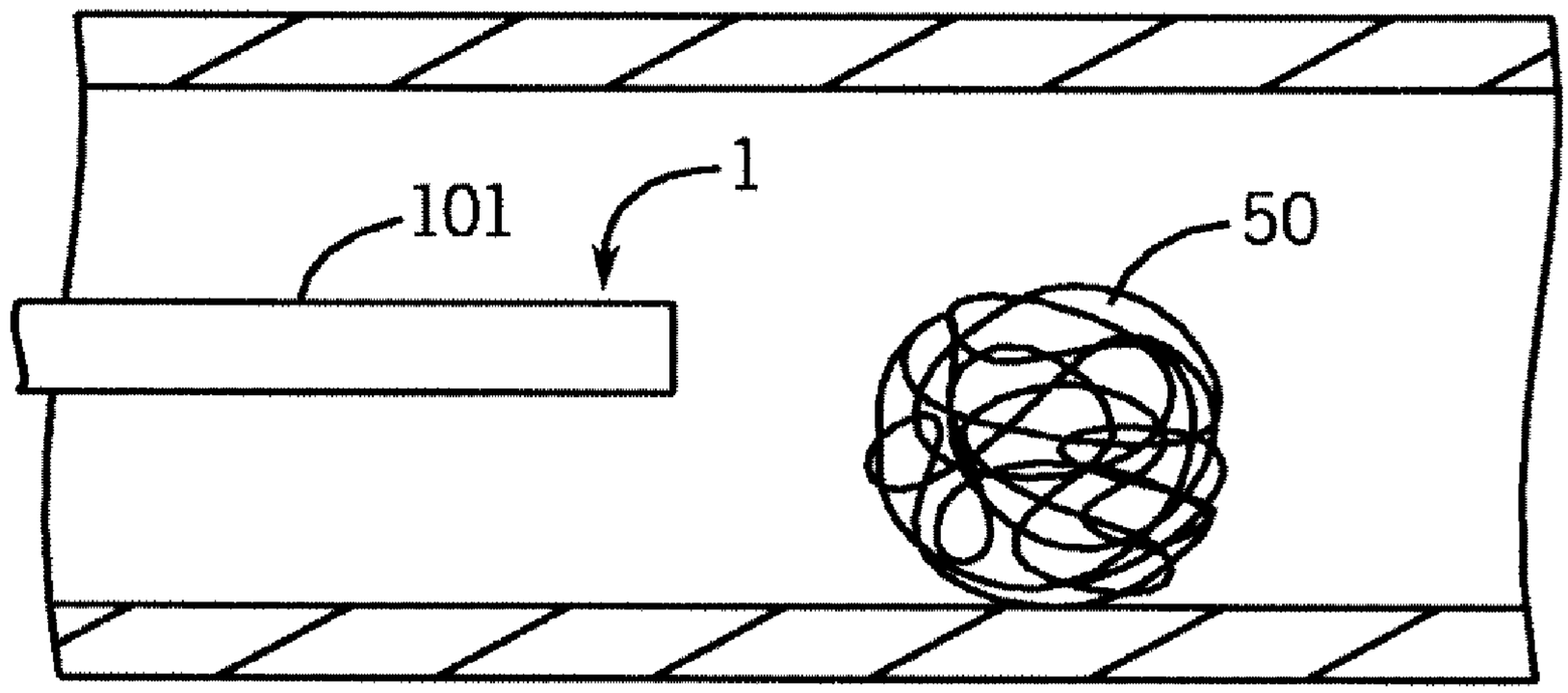


FIG. 1

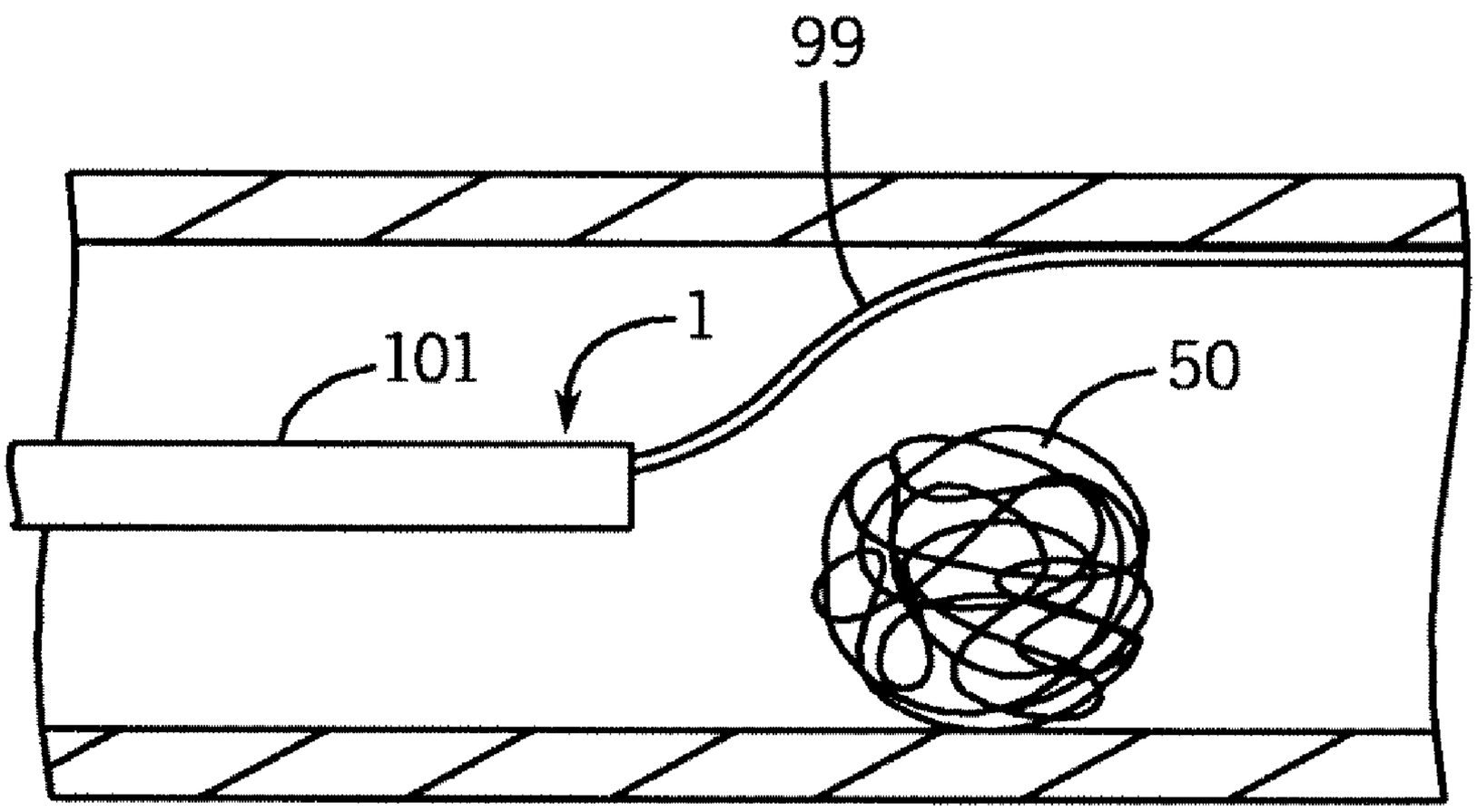
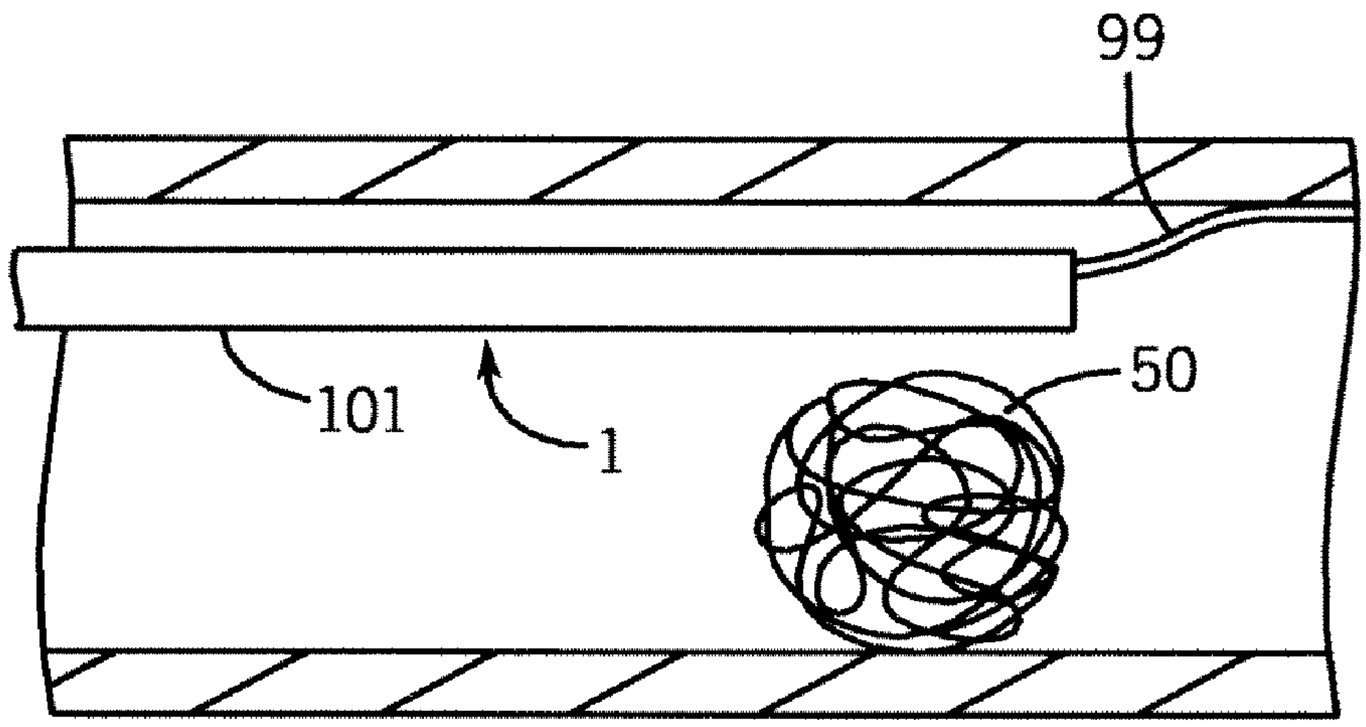


FIG. 2



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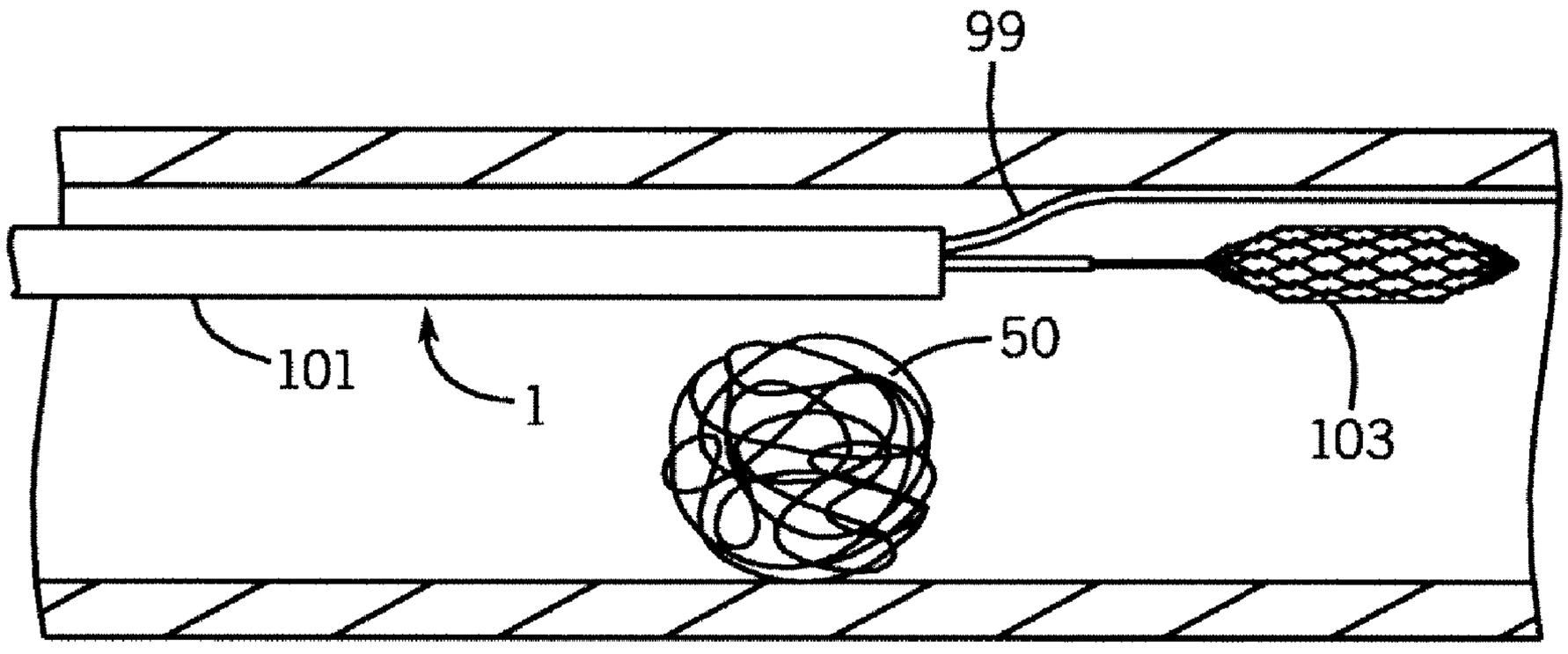

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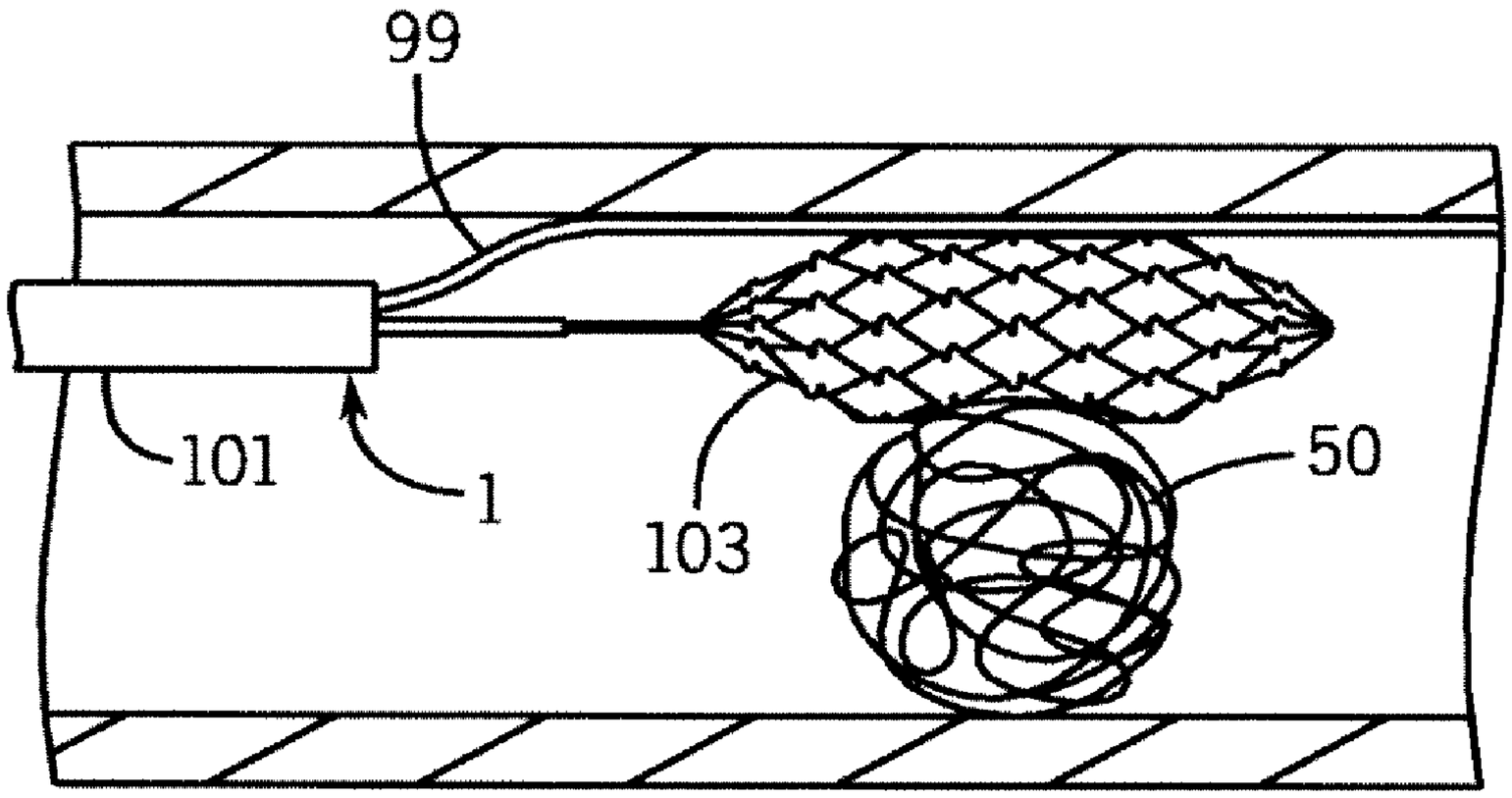

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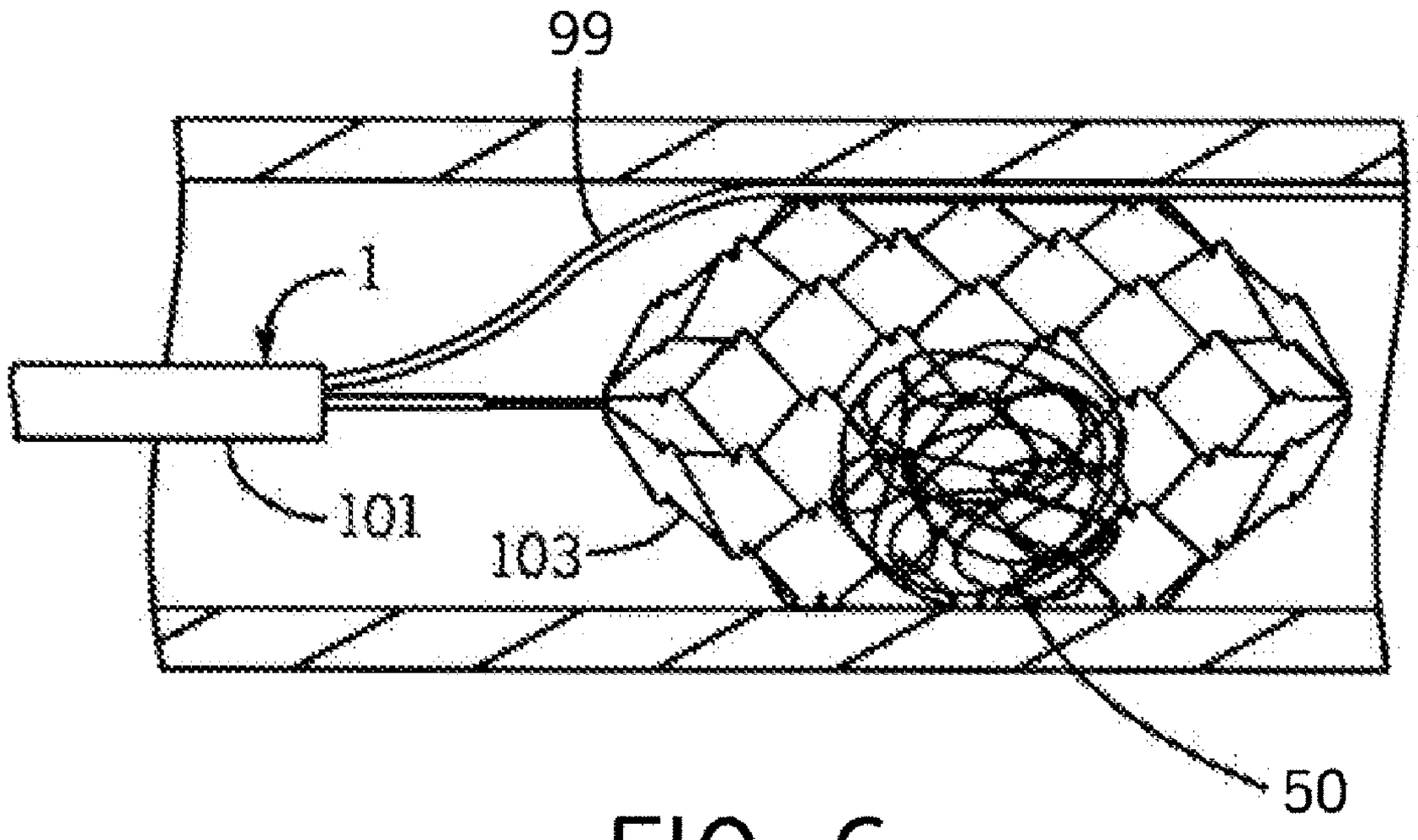

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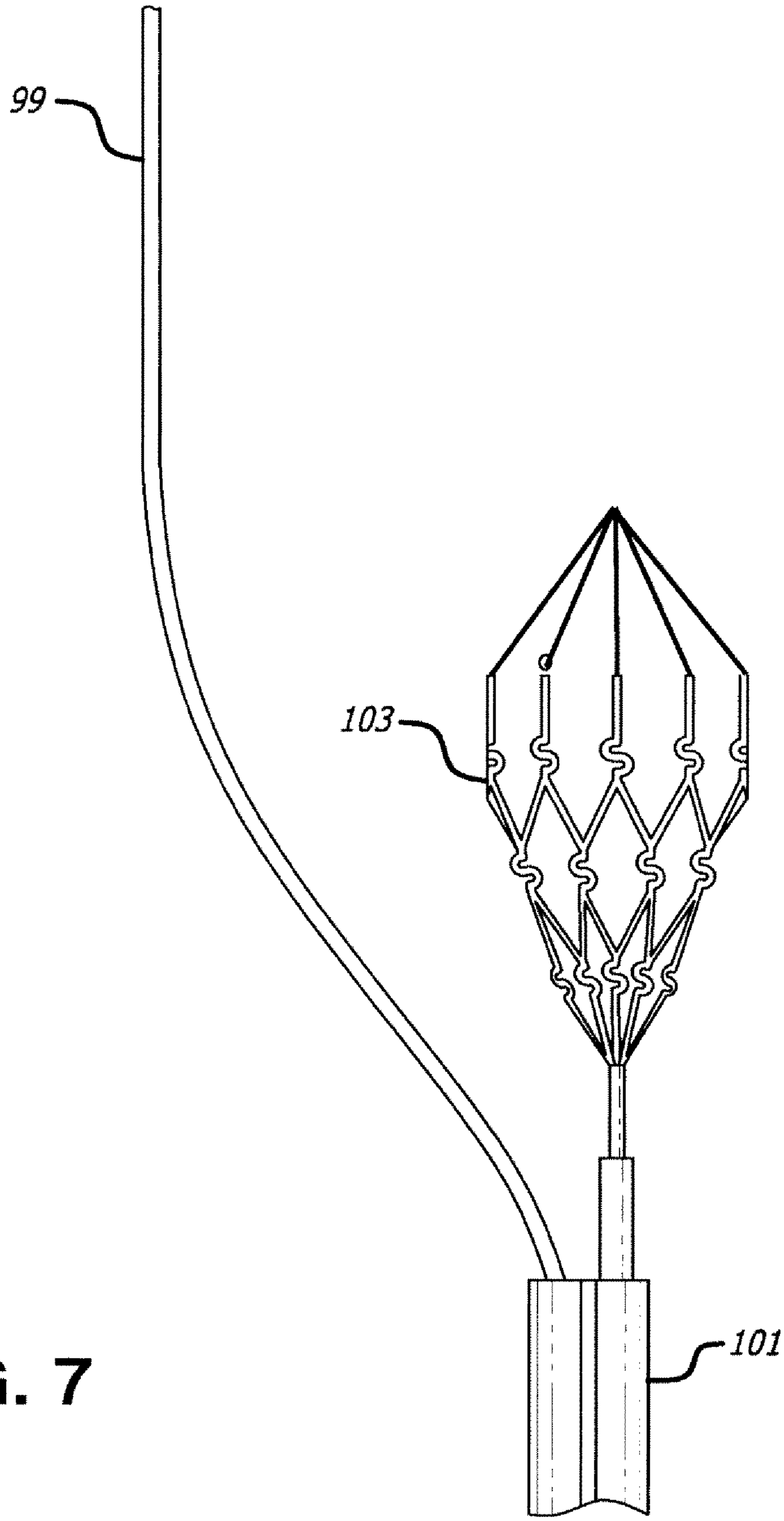

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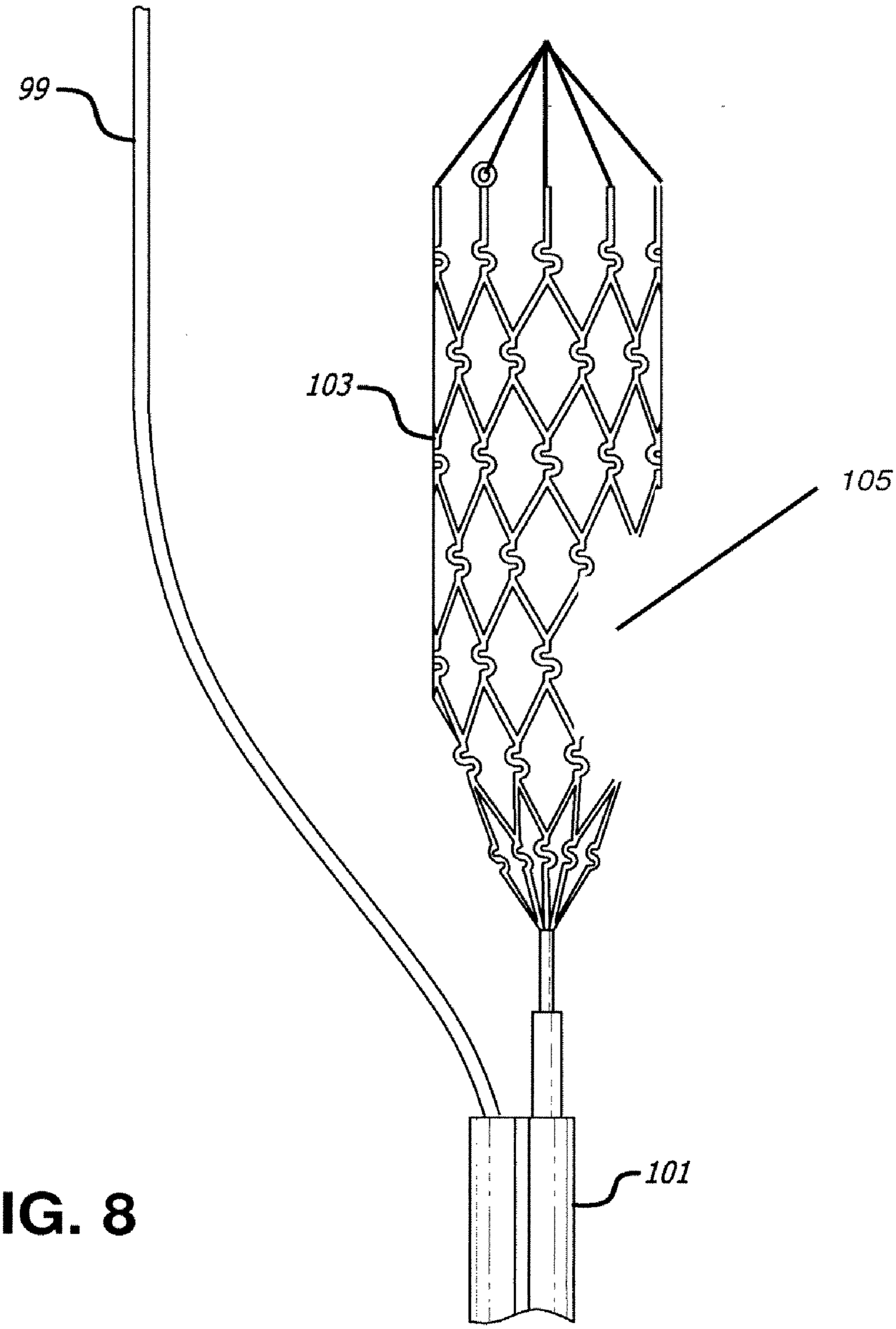

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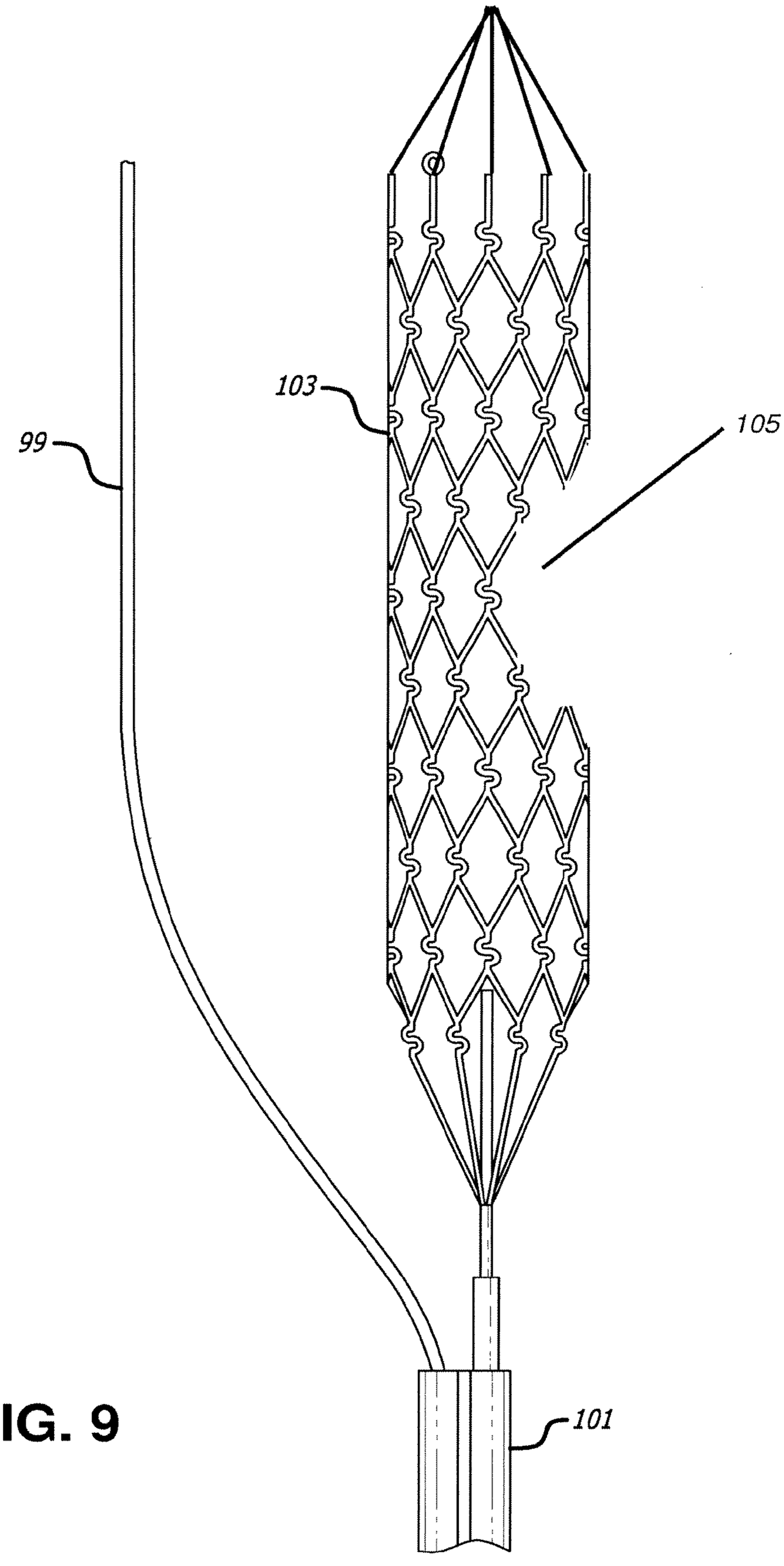

FIG. 9

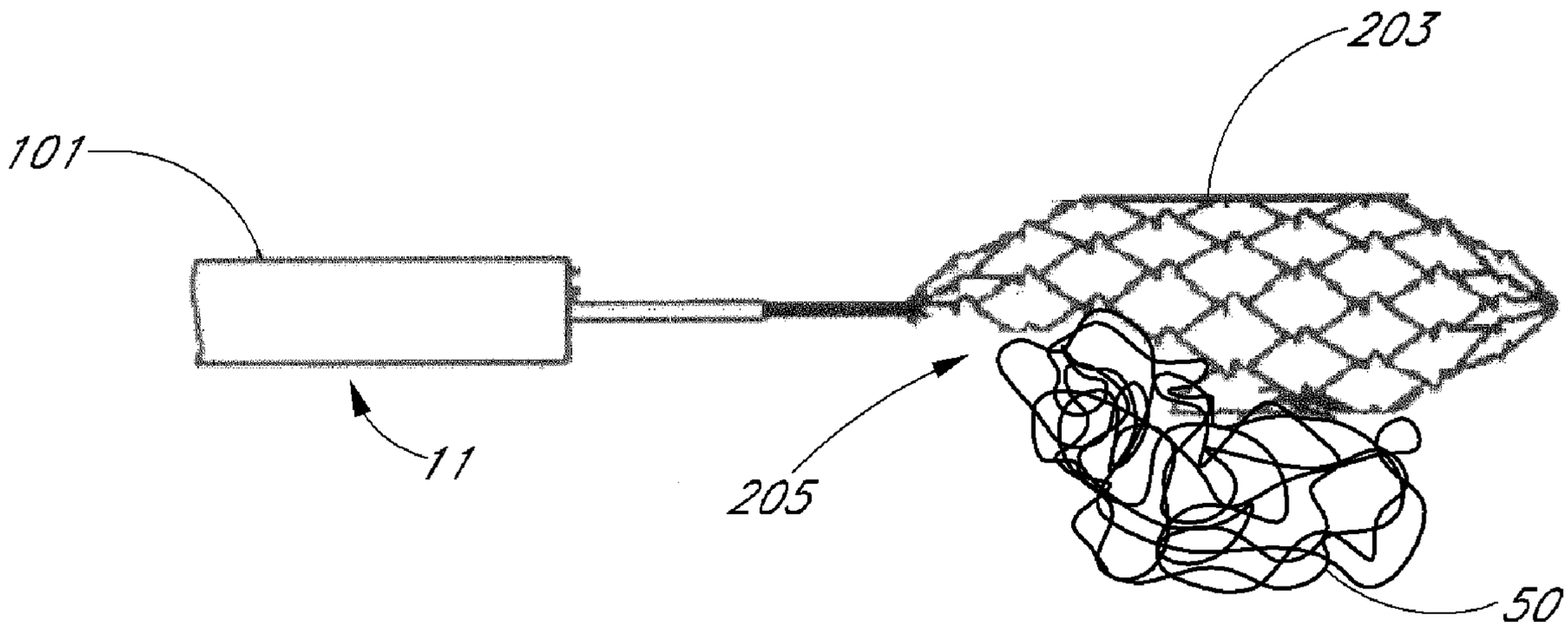

FIG. 10

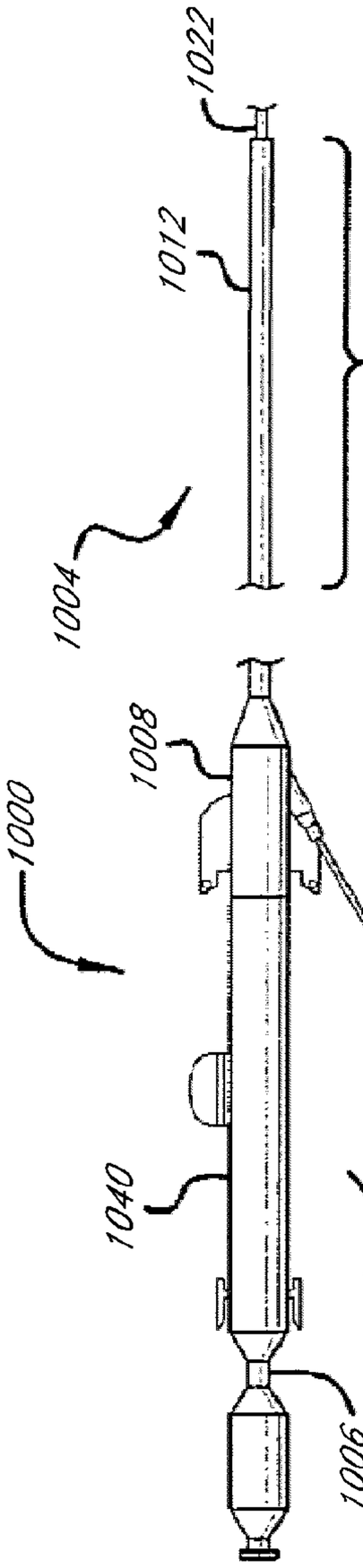
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FIG. 11

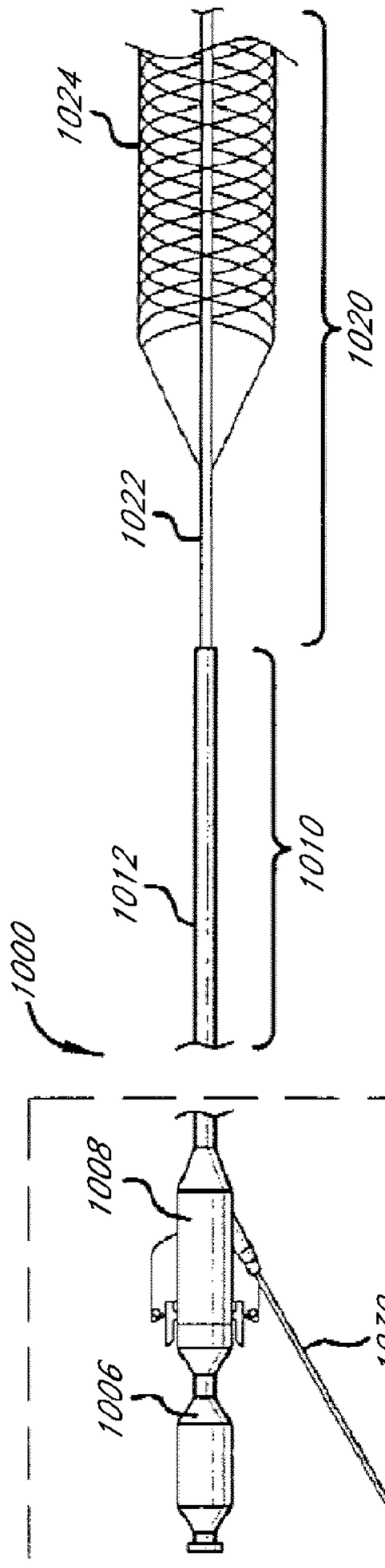
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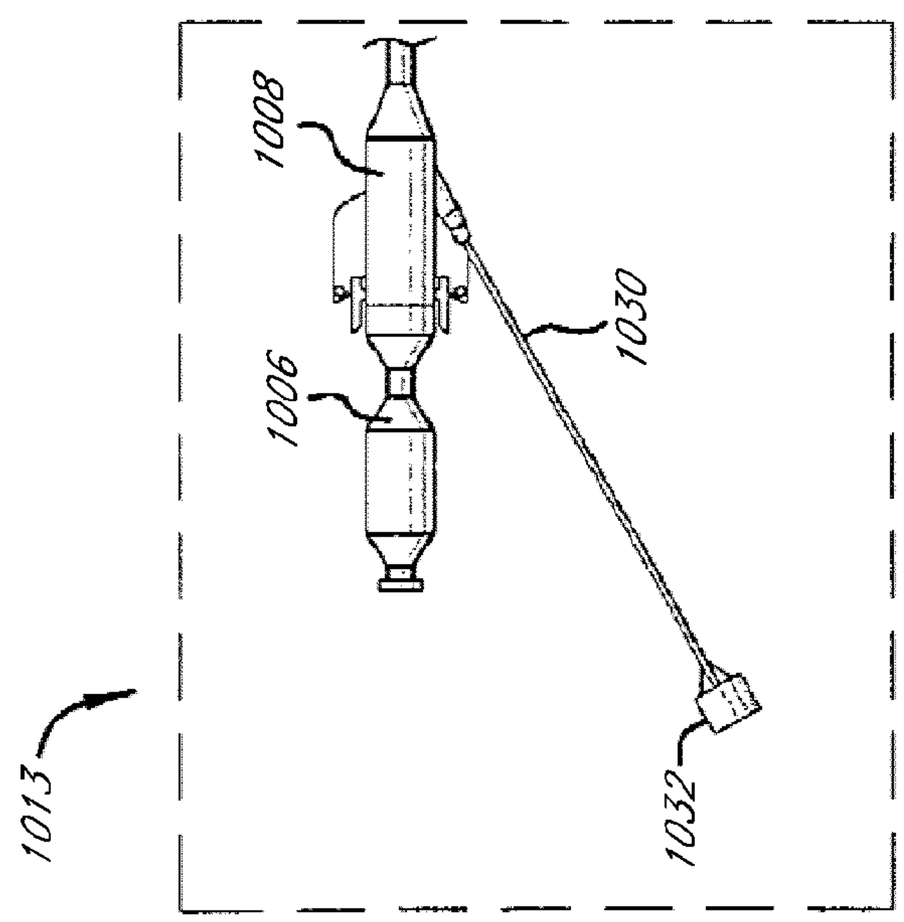
FIG. 12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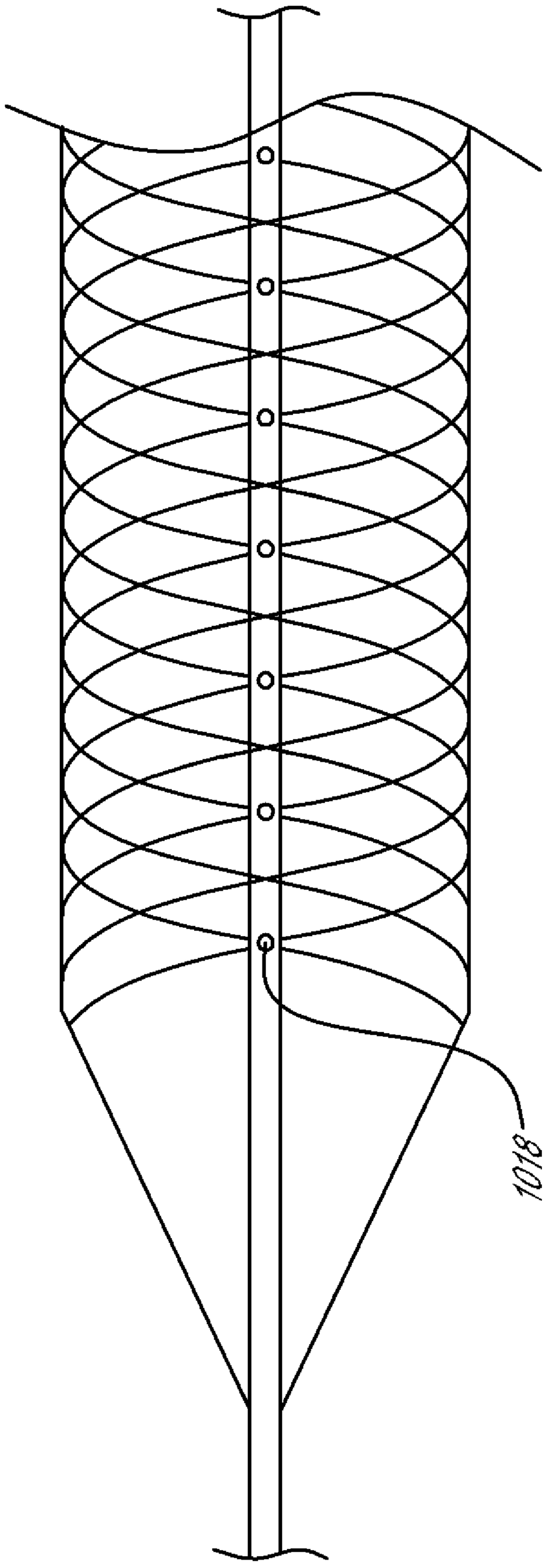


FIG. 12A

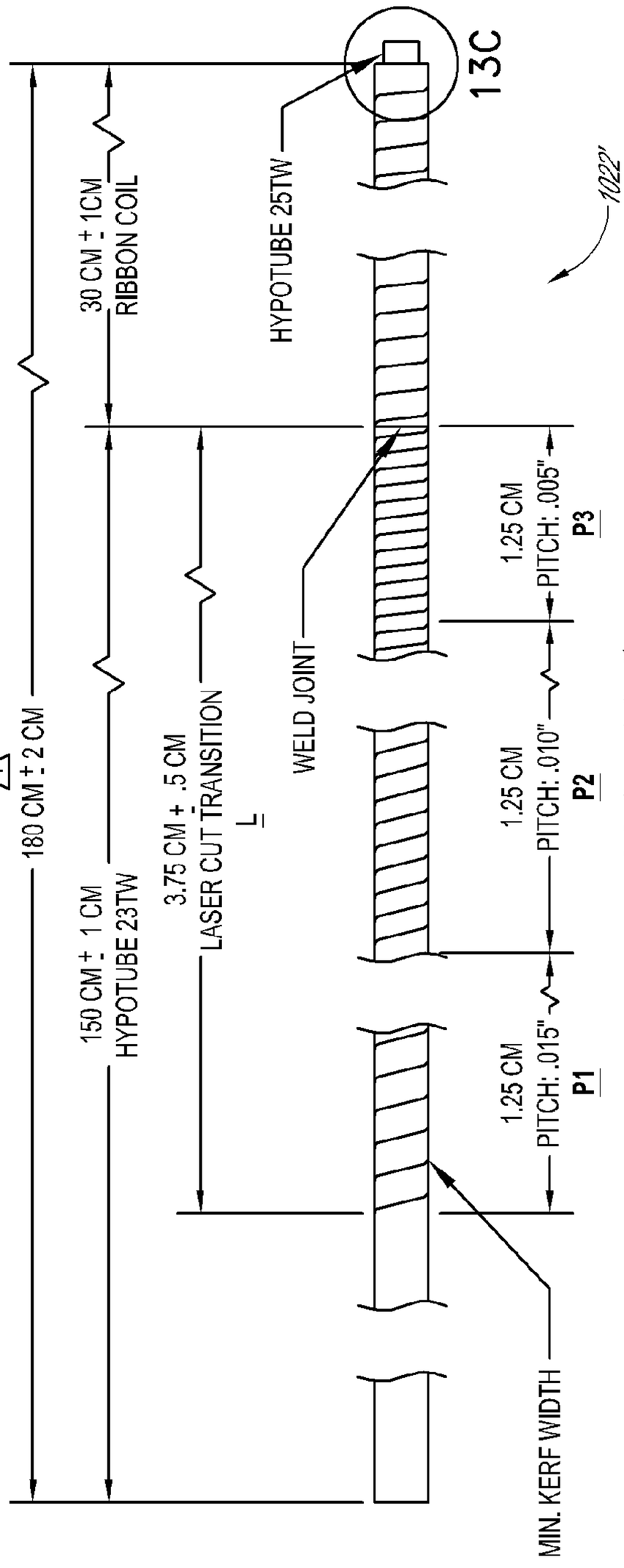


FIG. 13A

FIG. 13B

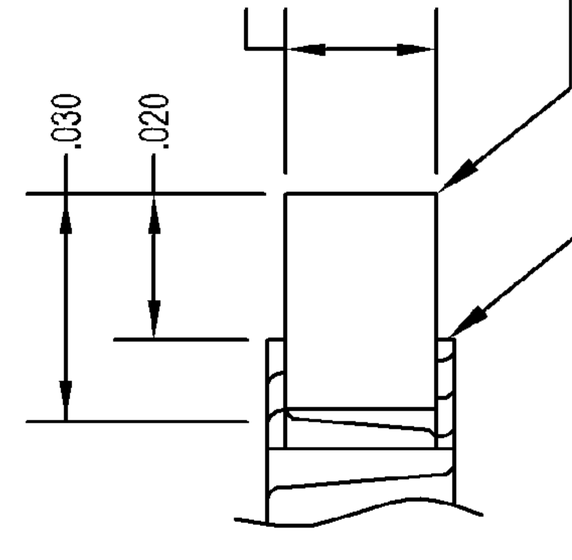


FIG. 13C

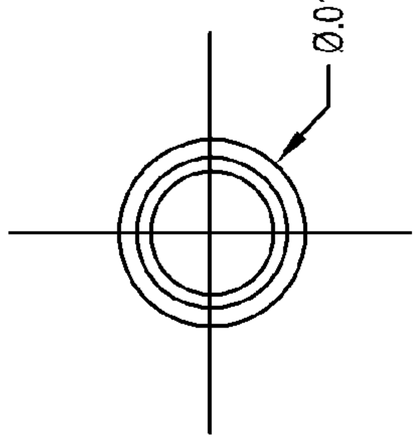


FIG. 13D

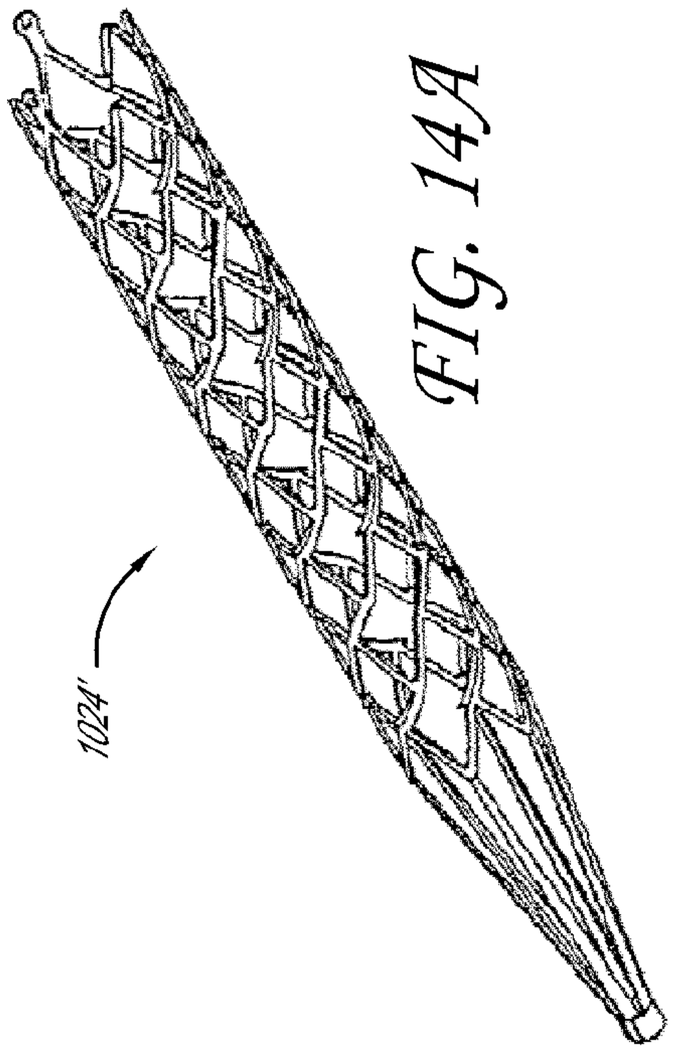


FIG. 14A

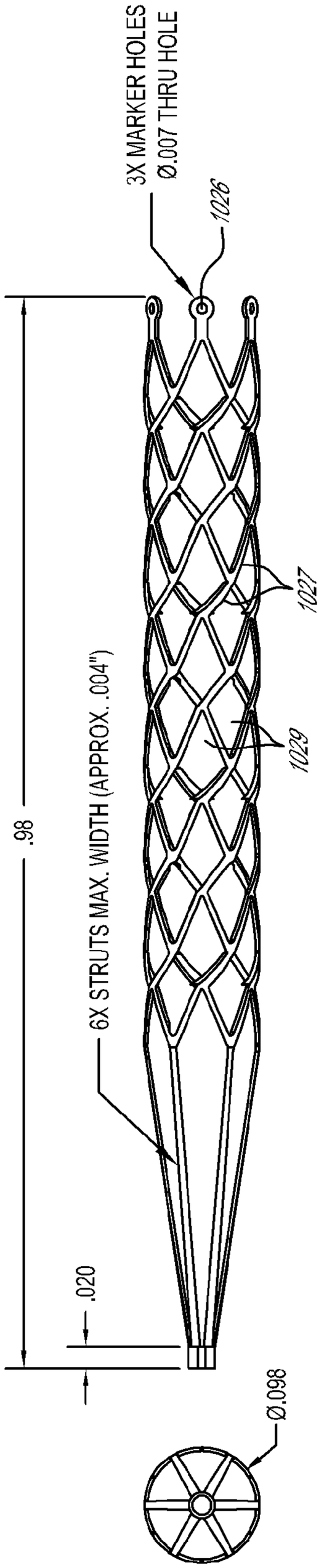


FIG. 14B

FIG. 14C

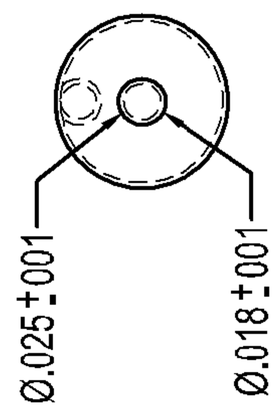


FIG. 15C

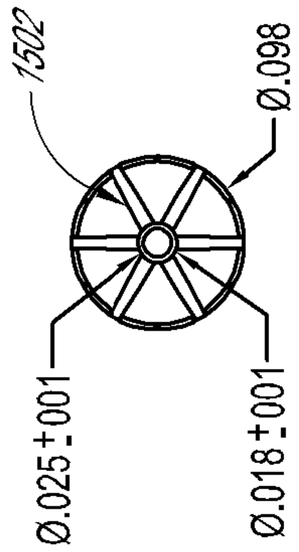


FIG. 15D

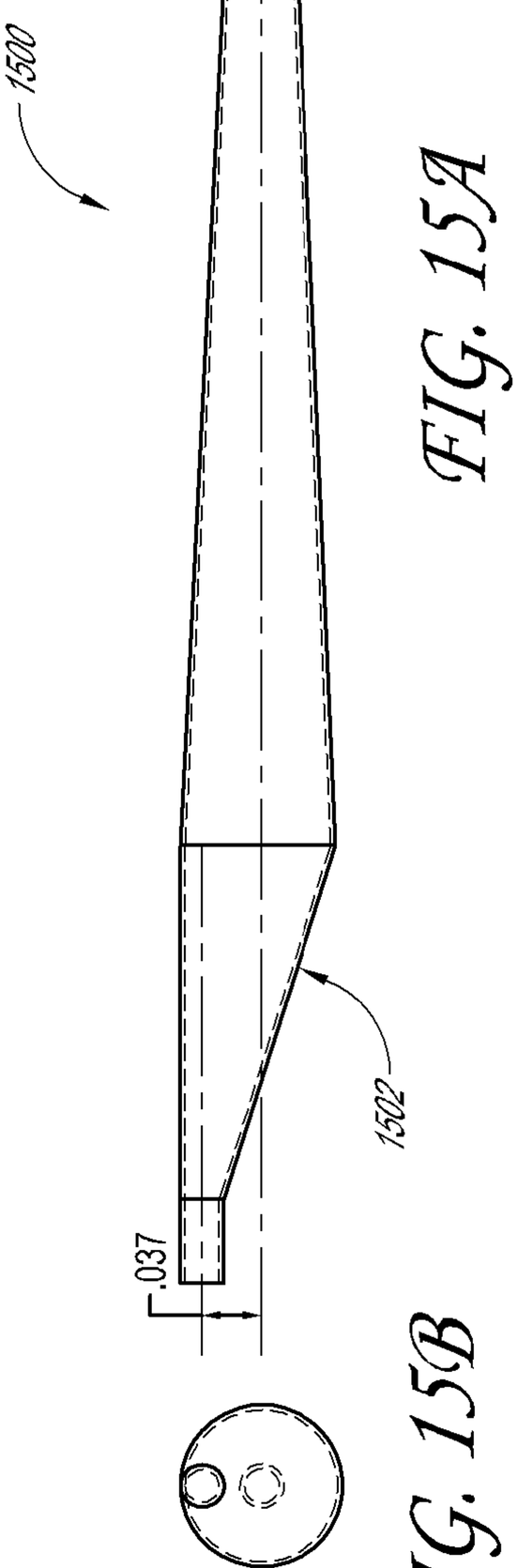
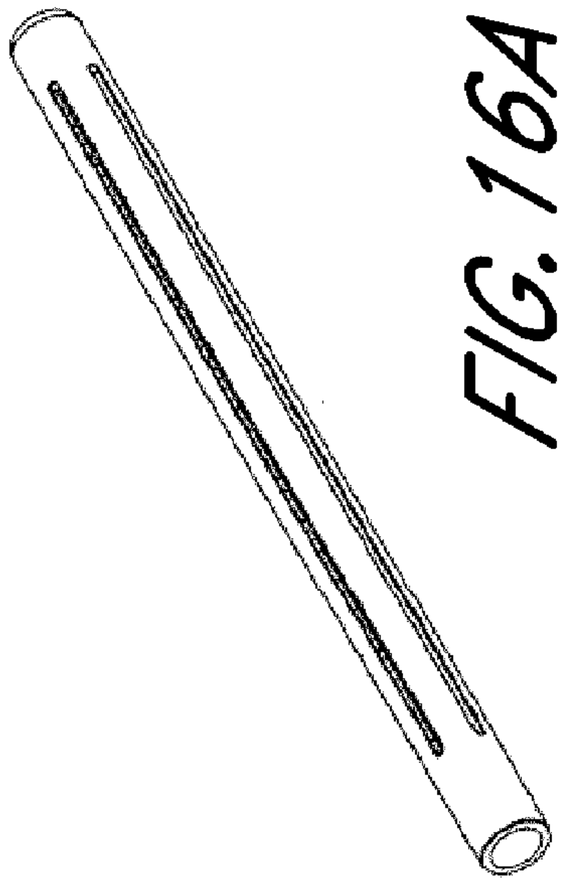


FIG. 15A

FIG. 15B



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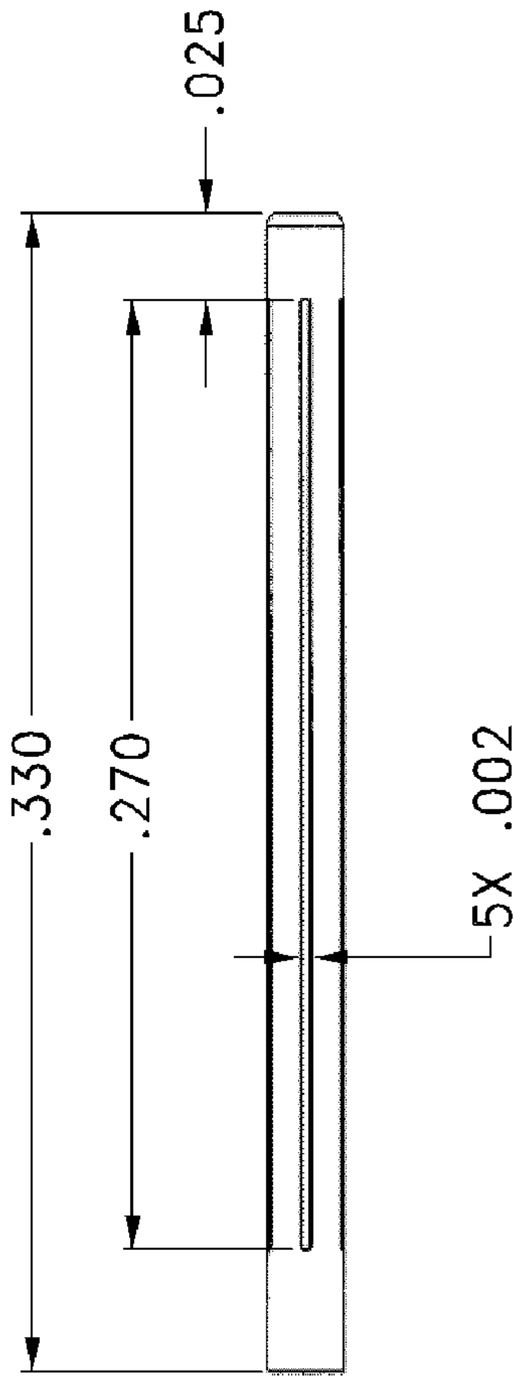


FIG. 16B

FIG. 16C

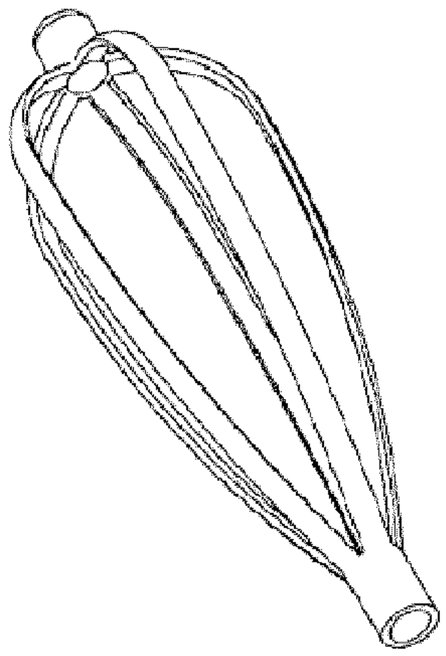


FIG. 16D

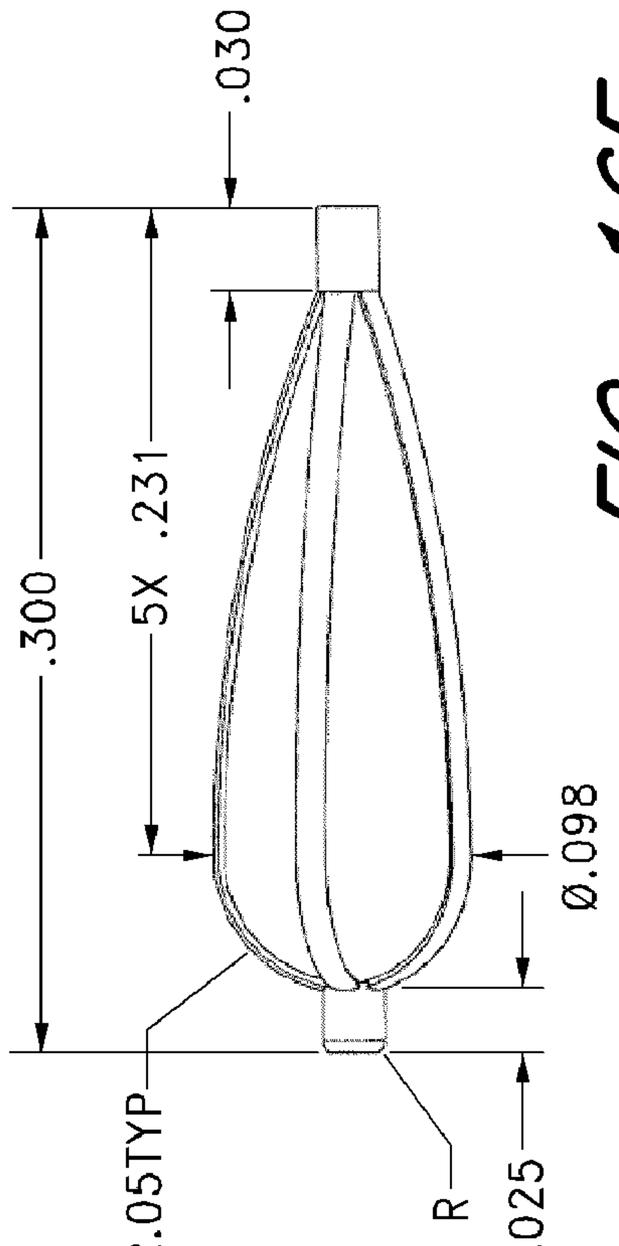


FIG. 16E

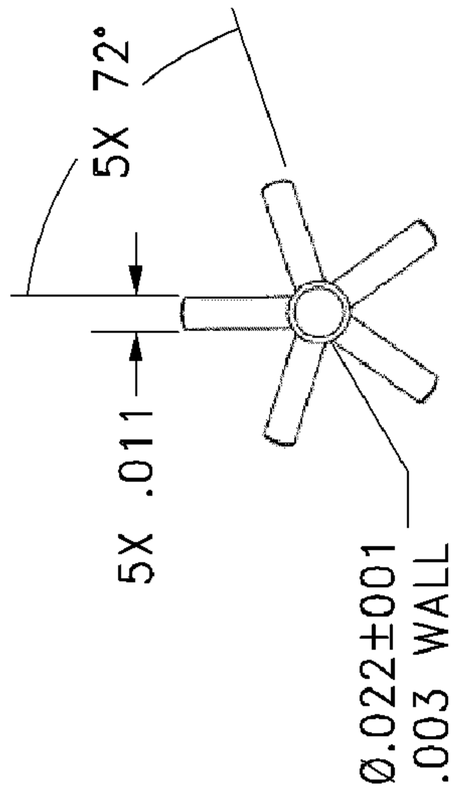


FIG. 16F

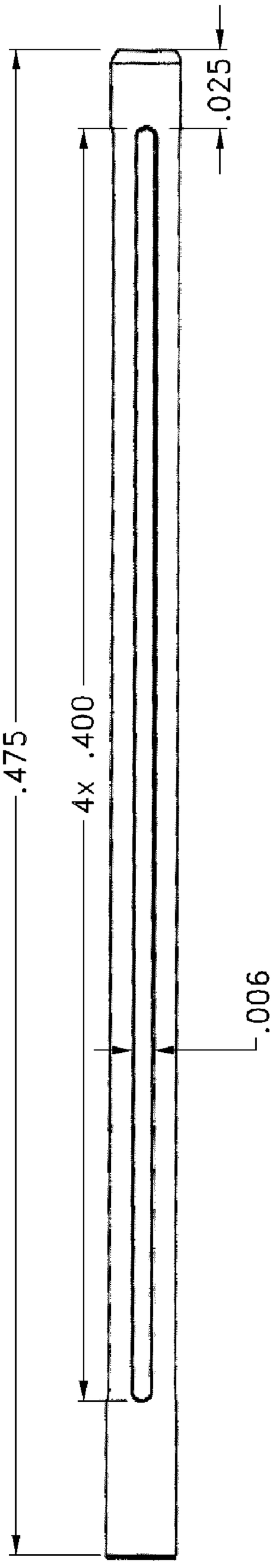


FIG. 17A

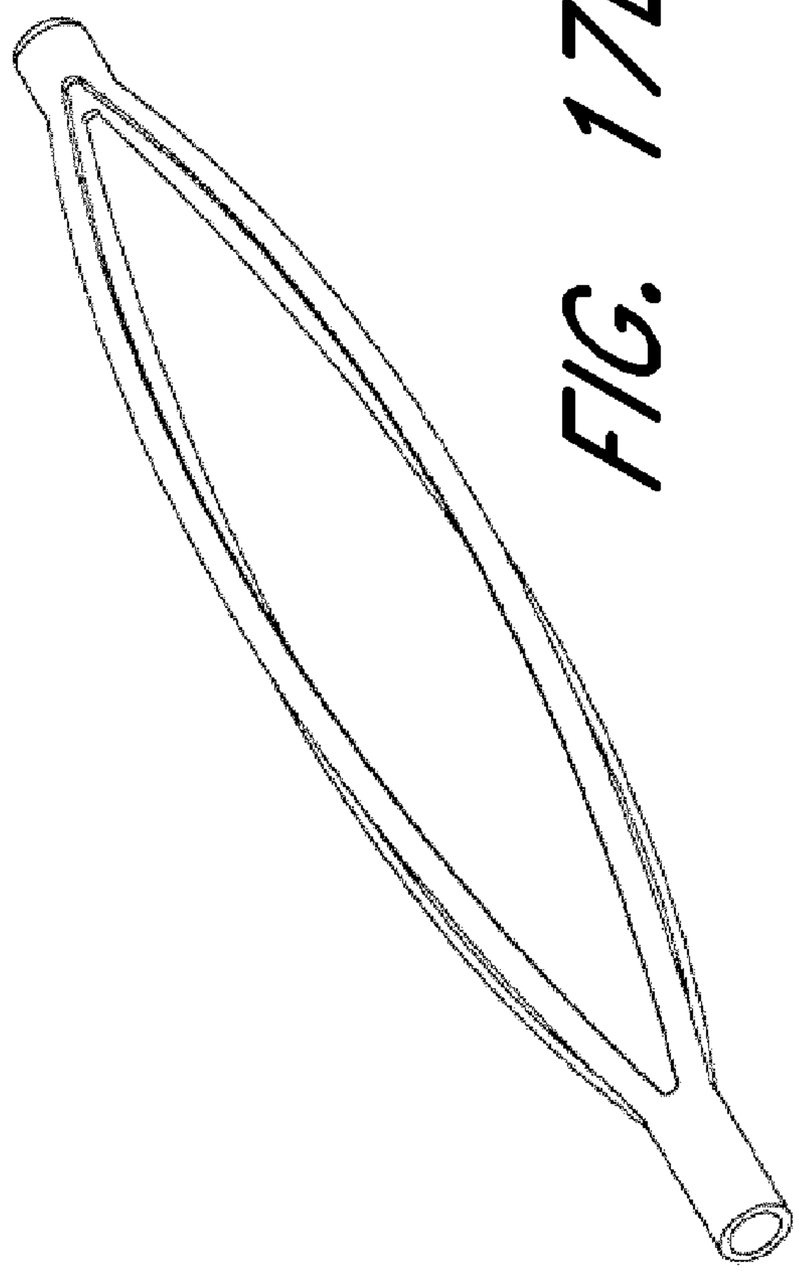


FIG. 17B

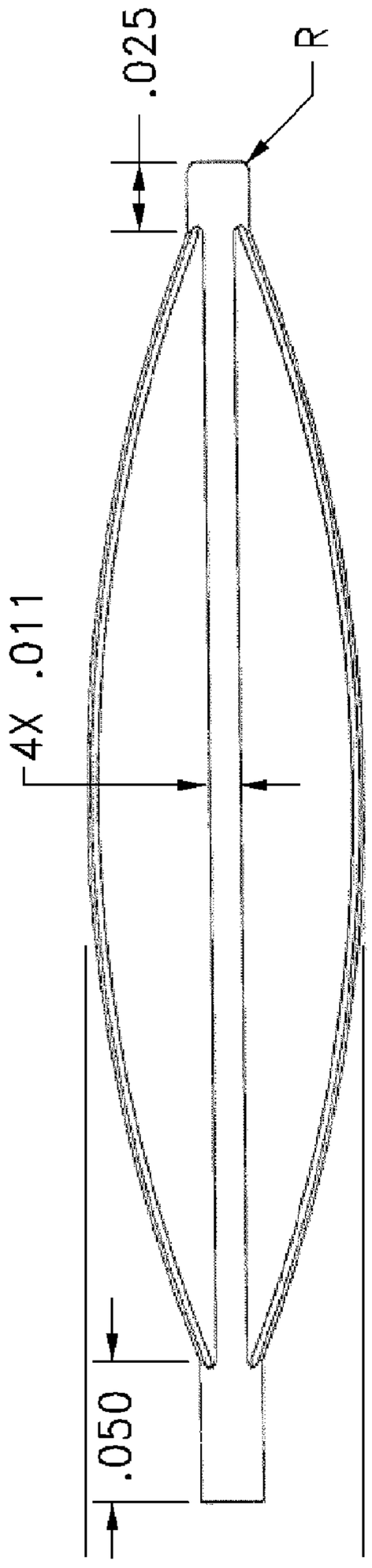
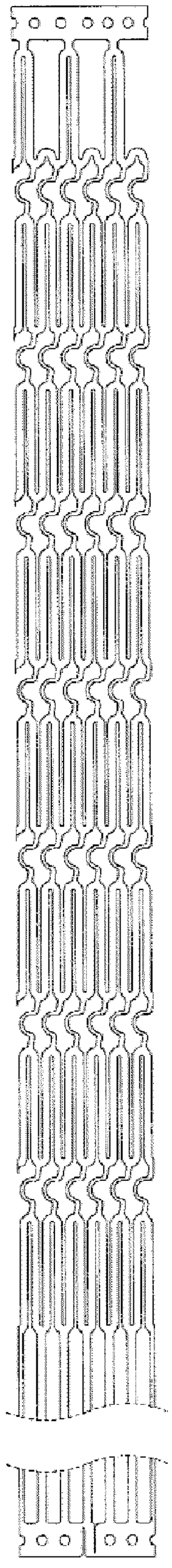


FIG. 17C



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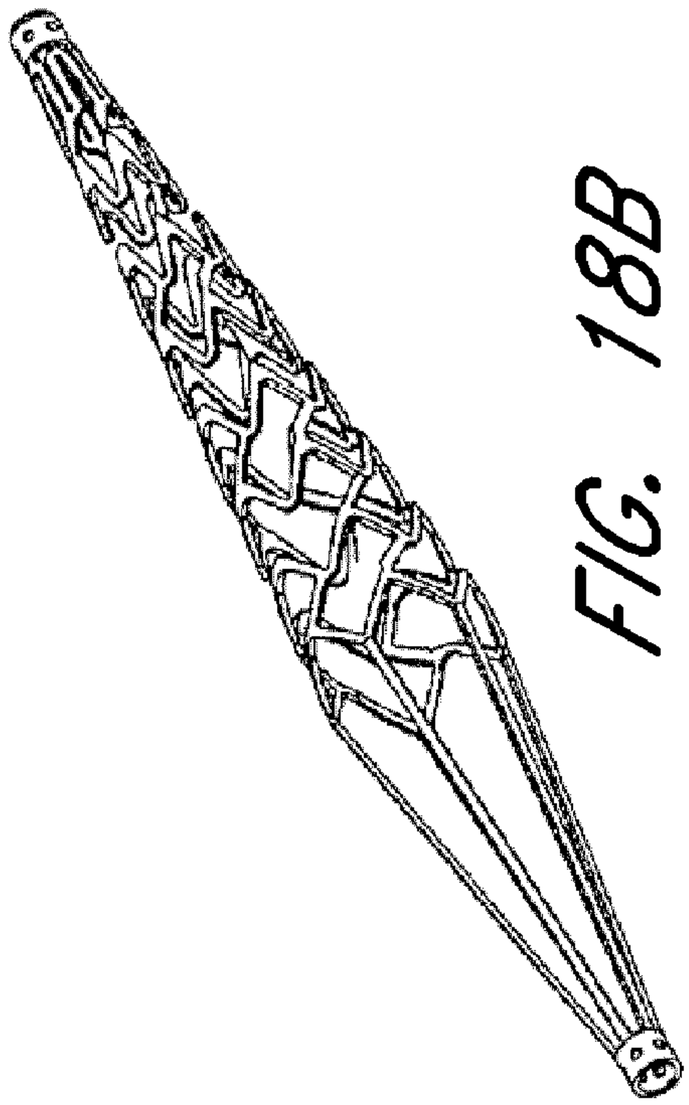
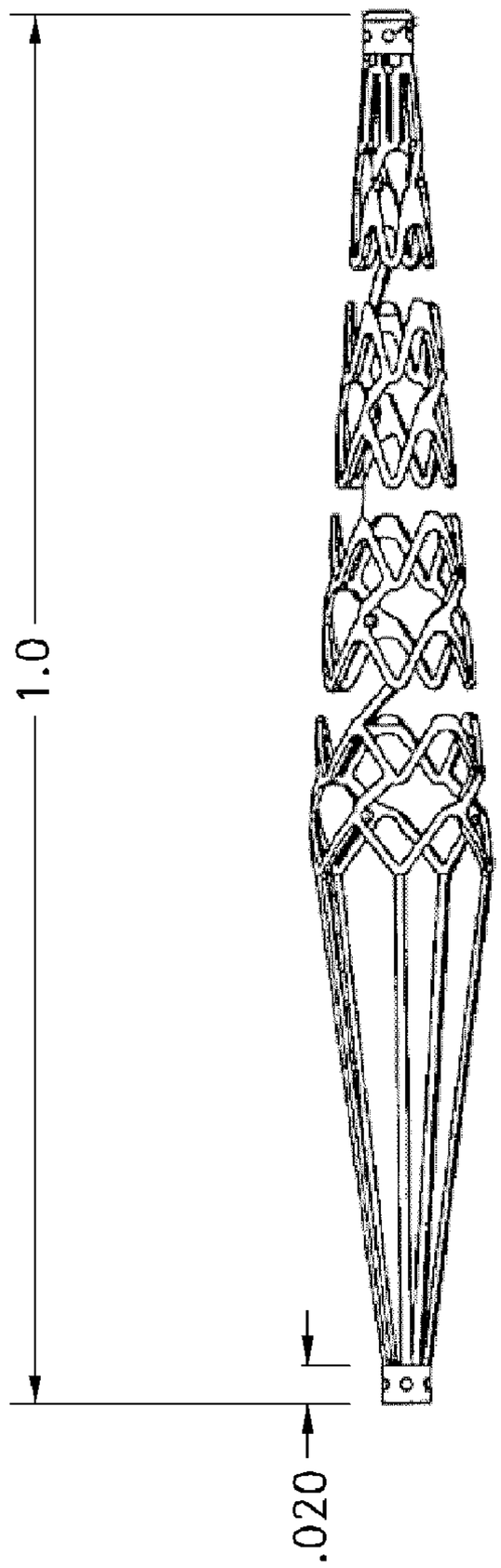


FIG. 18B



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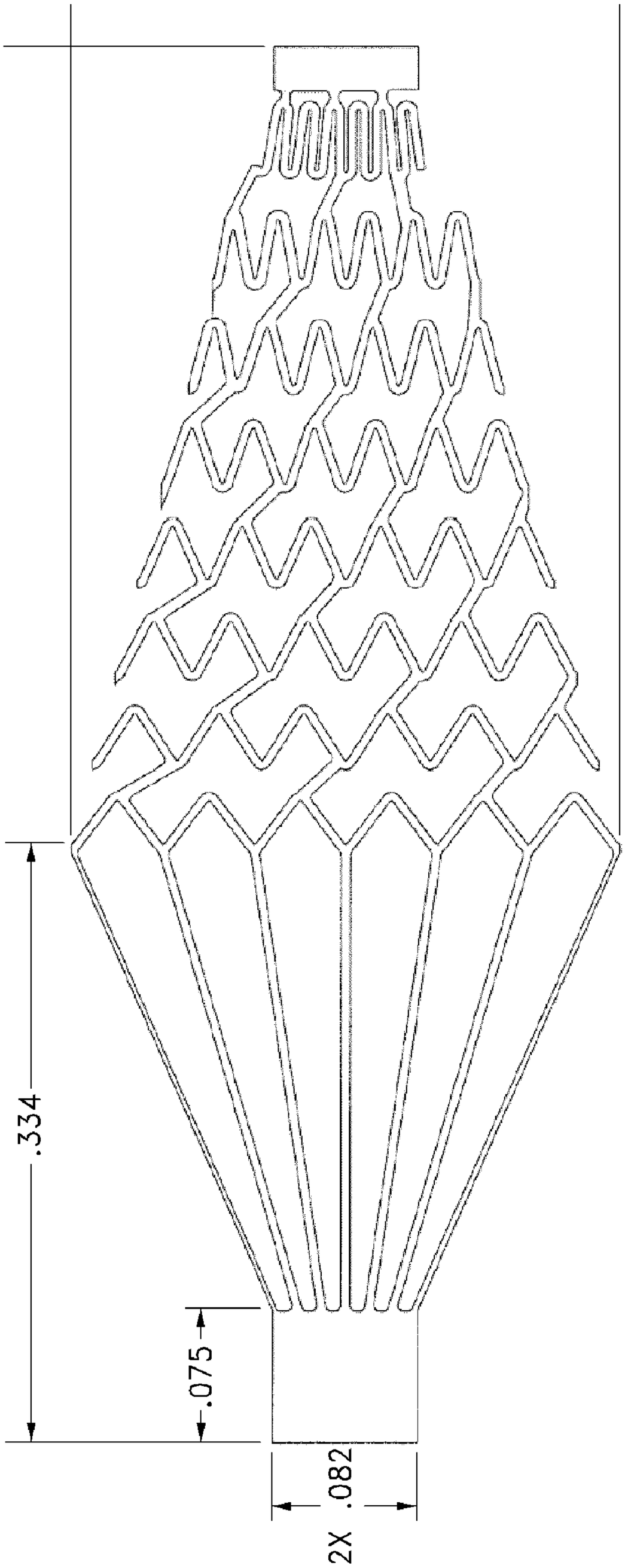

FIG. 18D

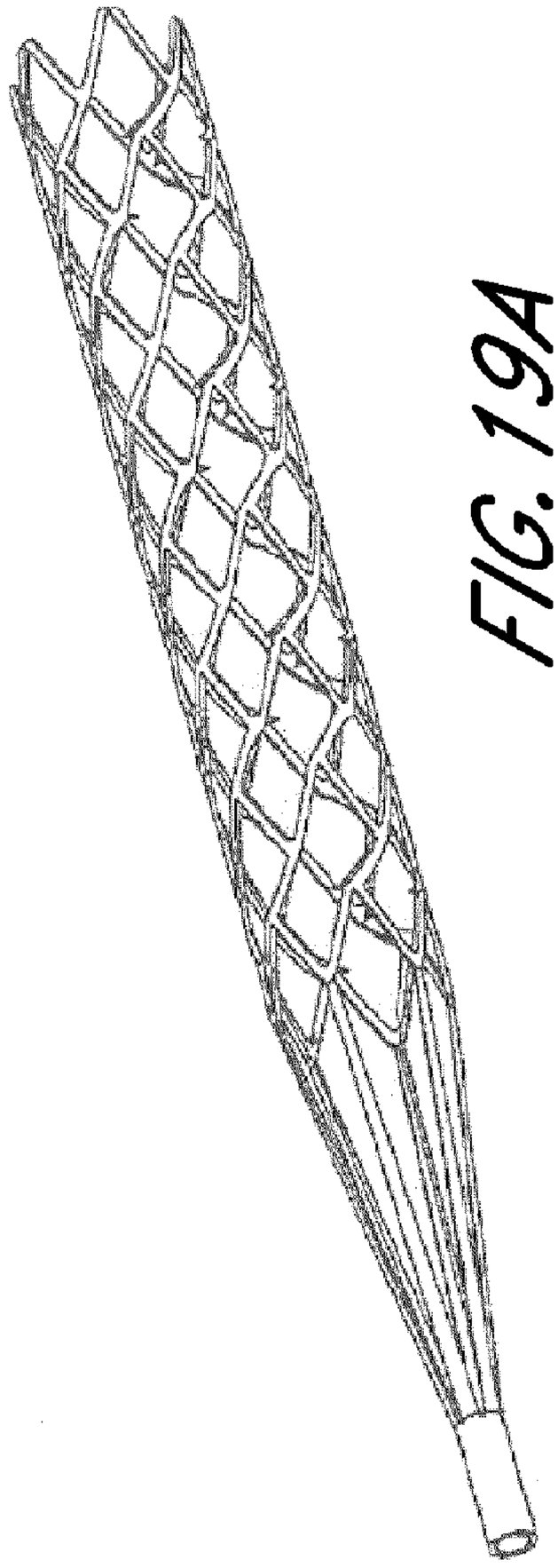

FIG. 19A

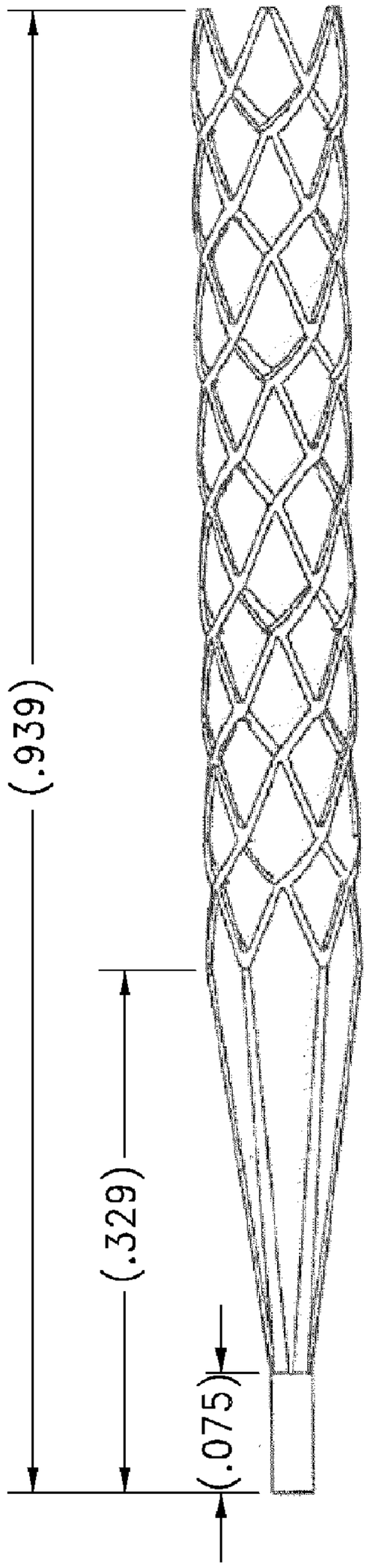

FIG. 19B

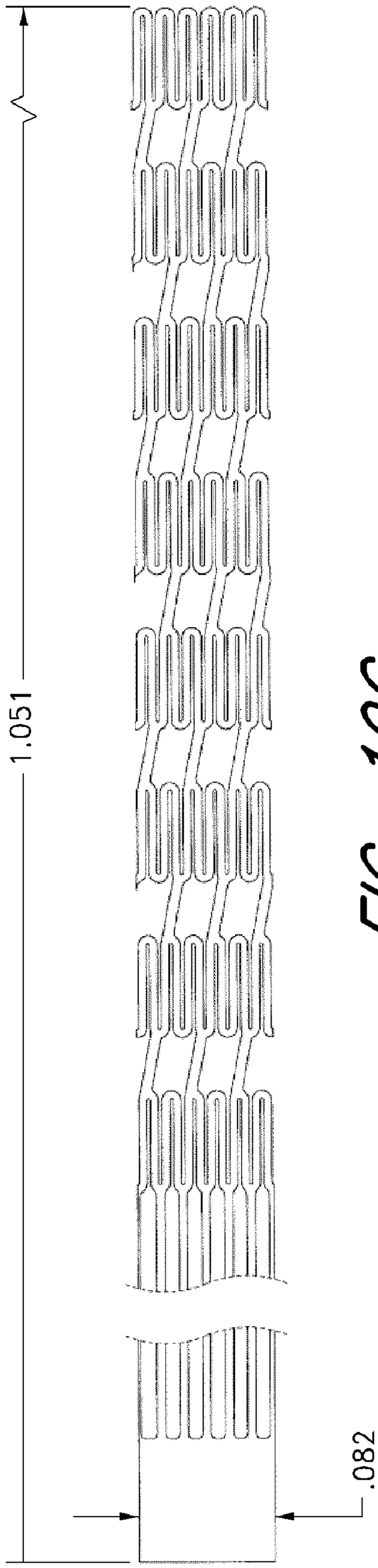

FIG. 19C

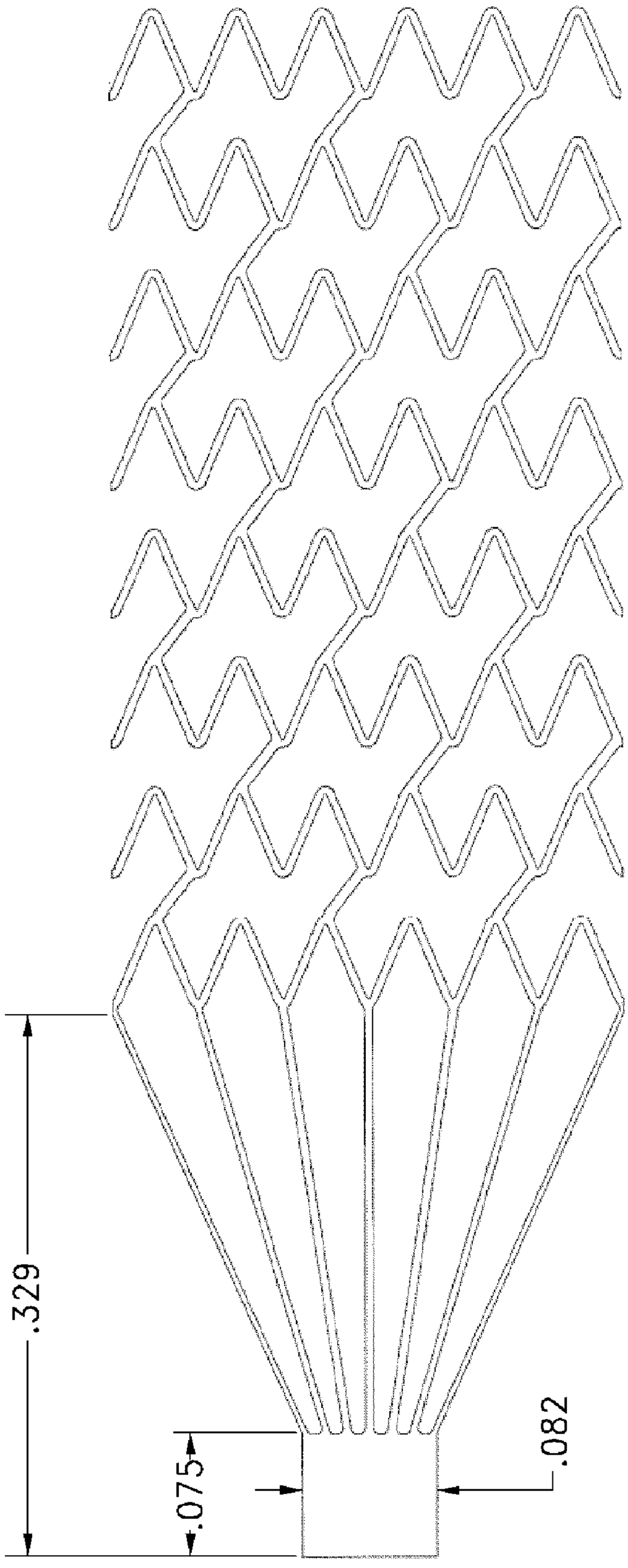

FIG. 19D

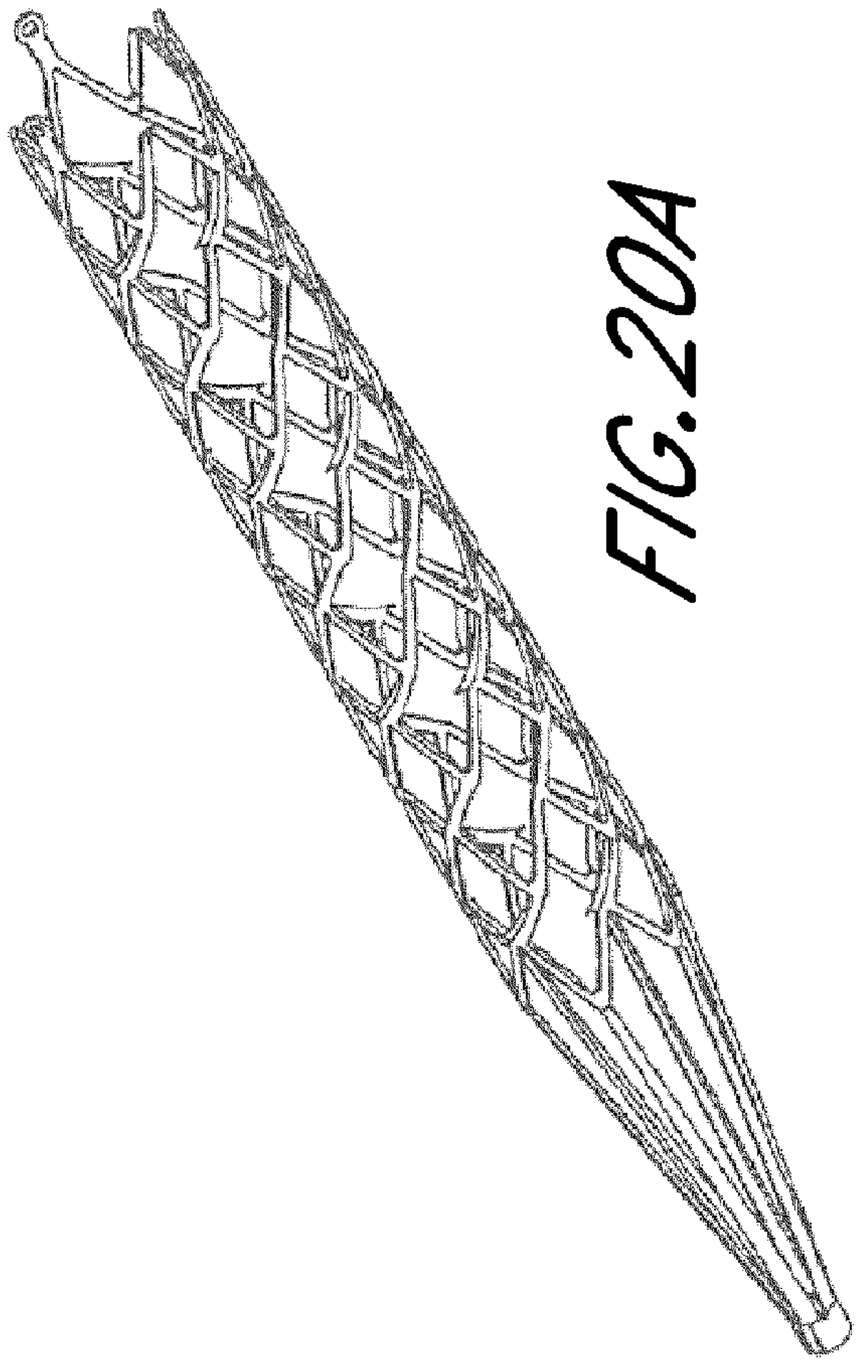

FIG. 20A

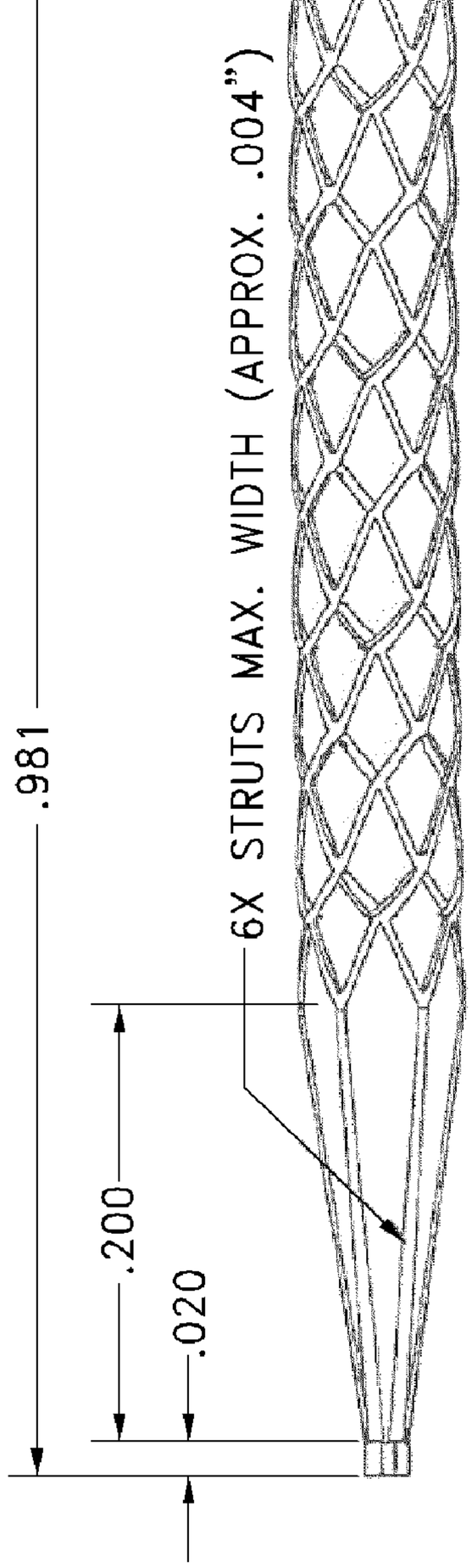

FIG. 20B

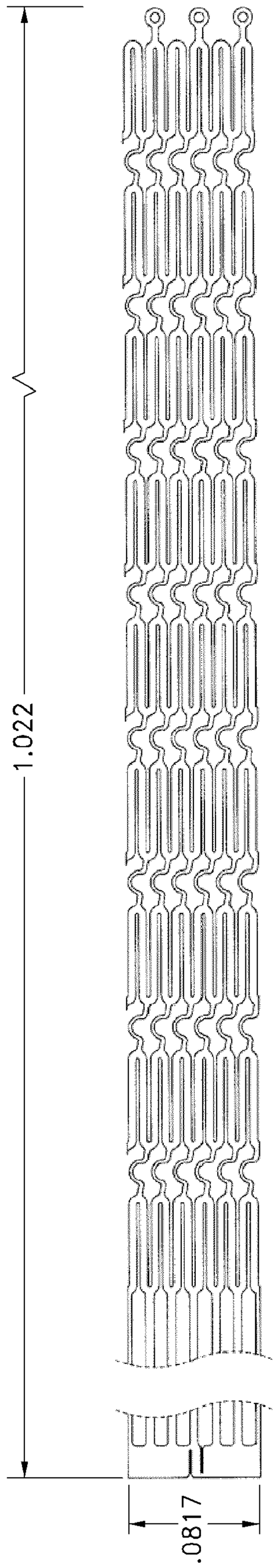

FIG. 20C

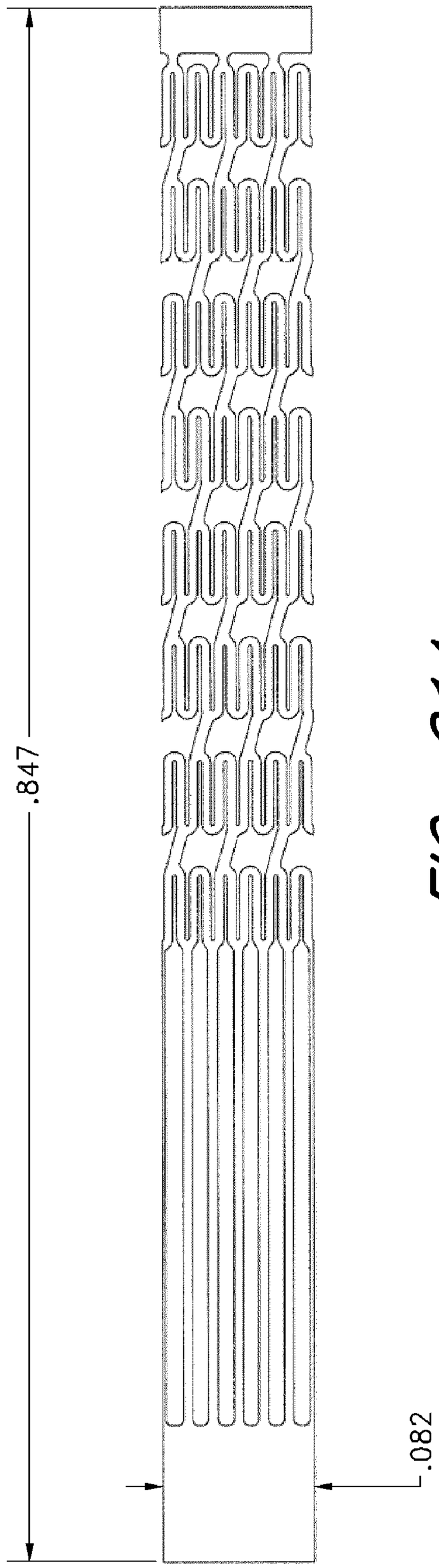

FIG. 21A

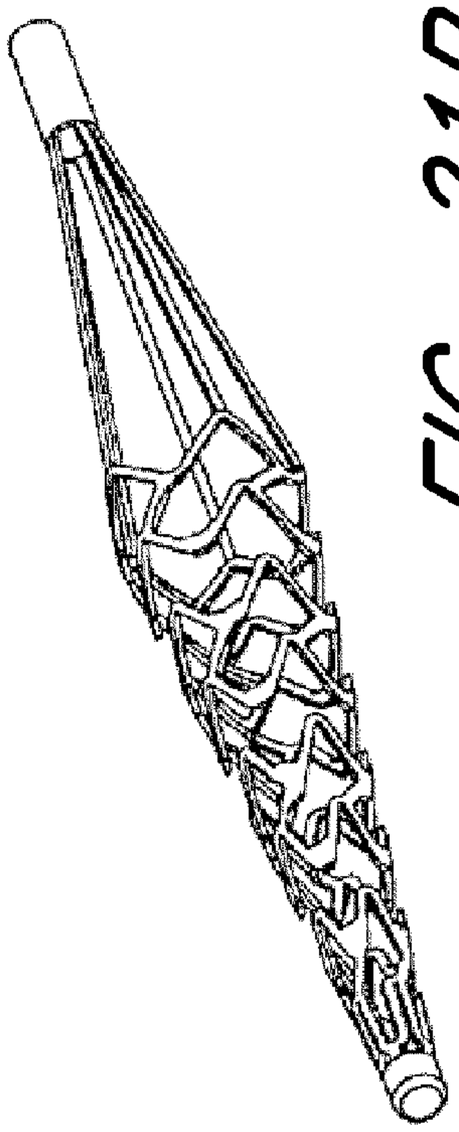

FIG. 21B

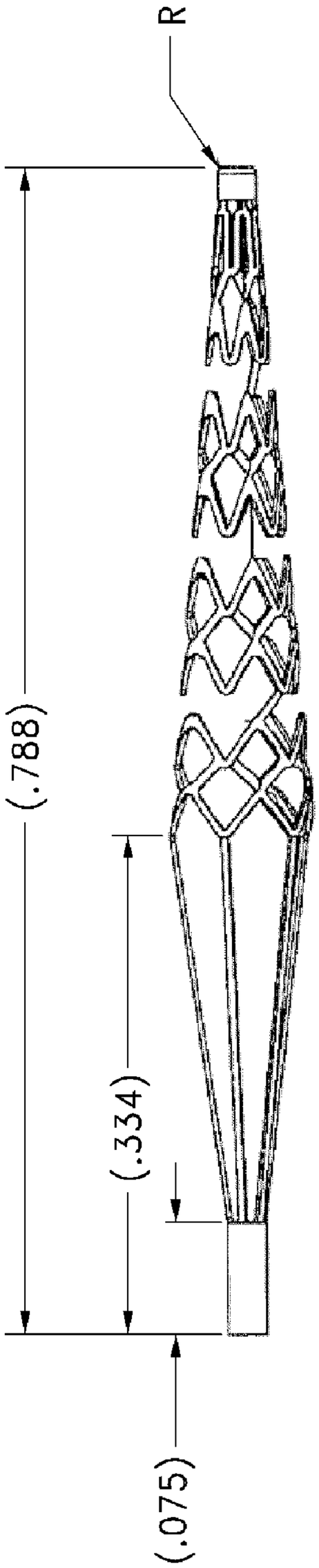

FIG. 21C

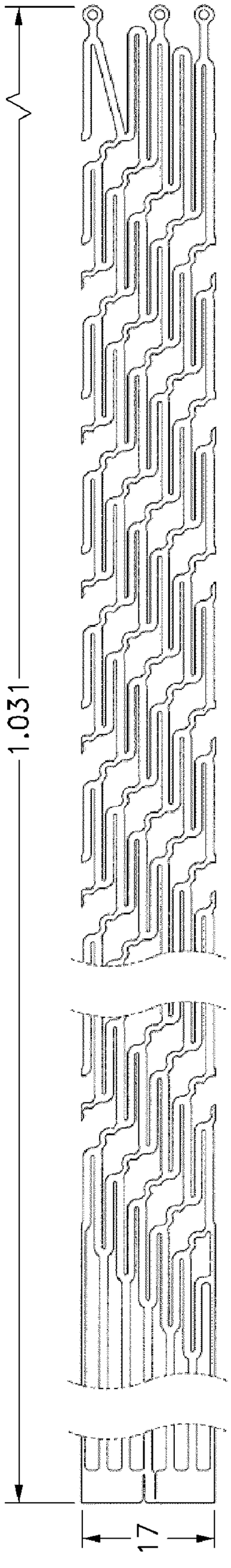

FIG. 22

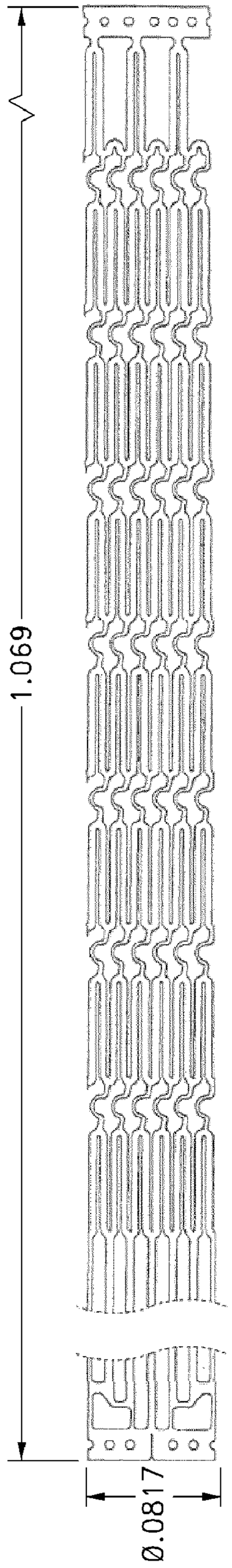

FIG. 23

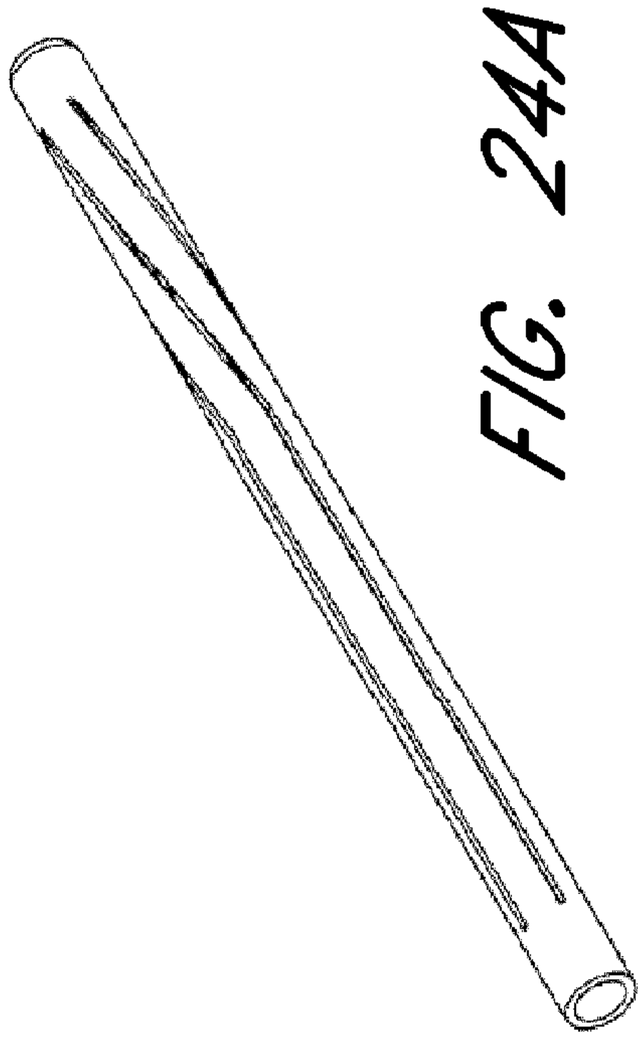

FIG. 24A

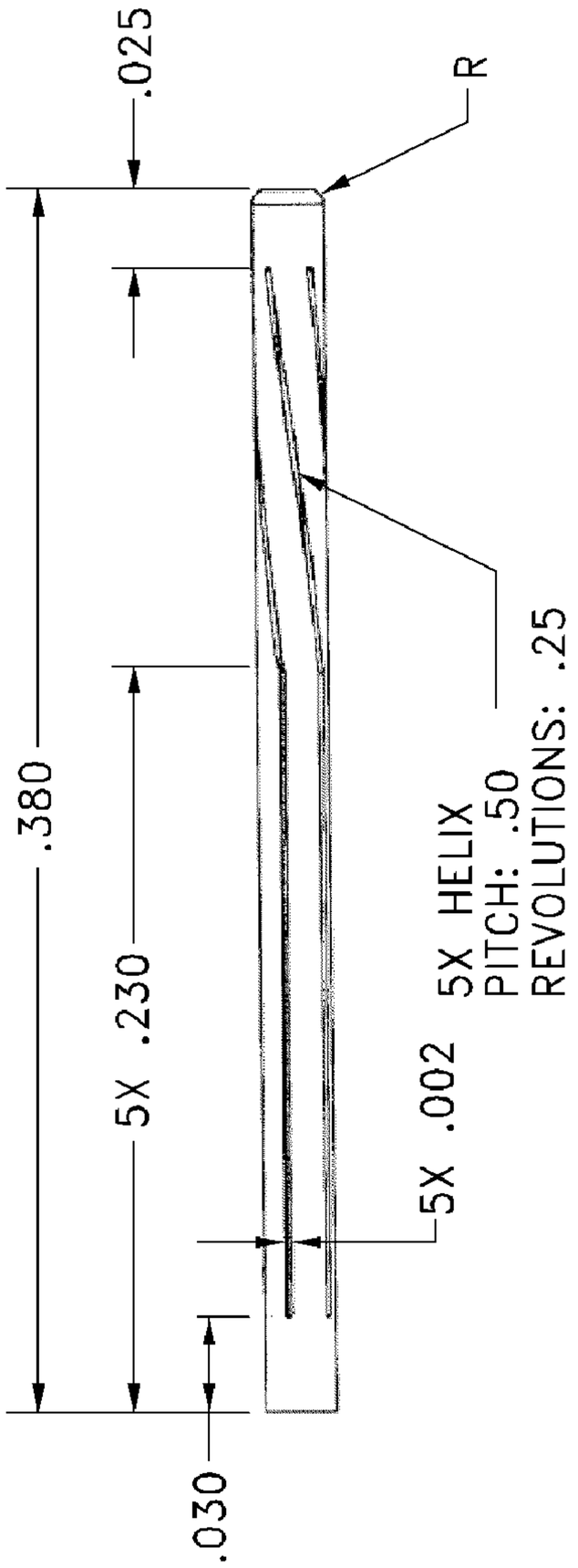

FIG. 24B

FIG. 24C

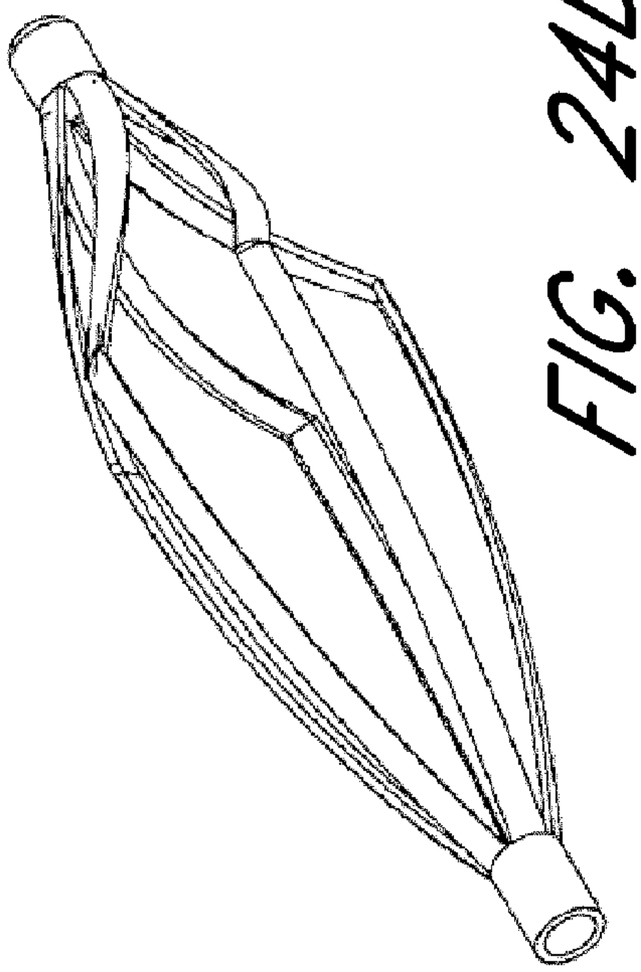

FIG. 24D

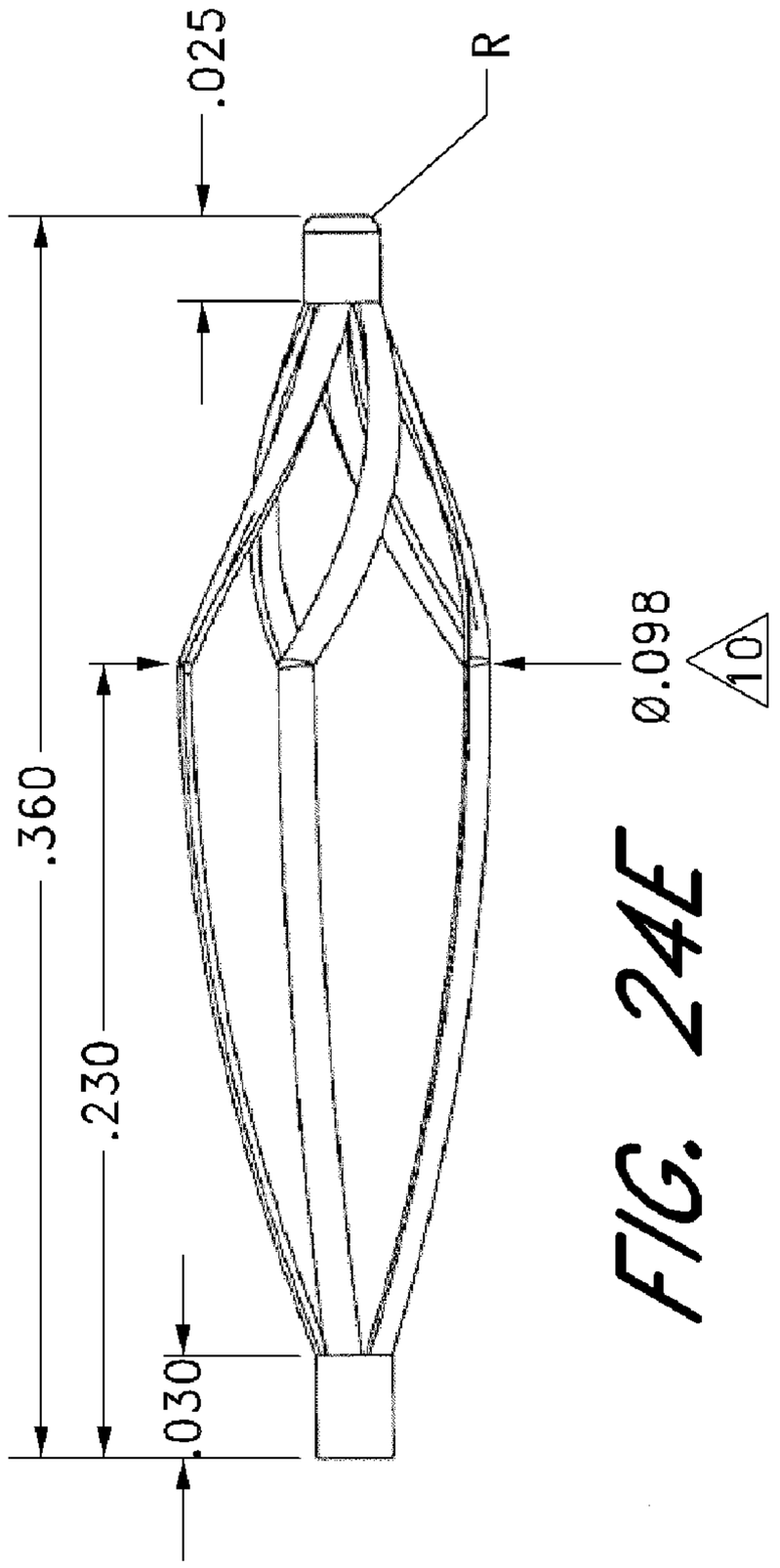

FIG. 24E

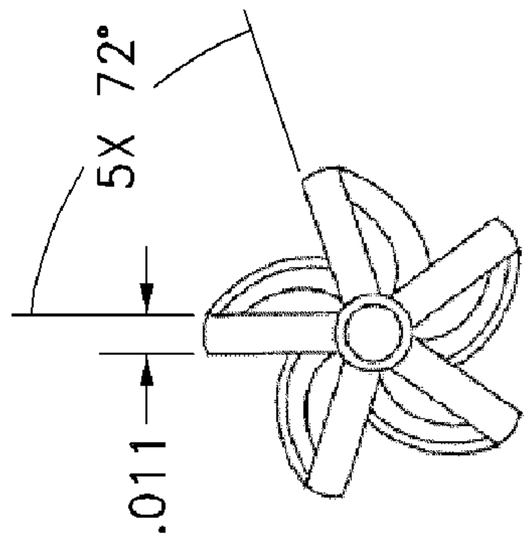

FIG. 24F

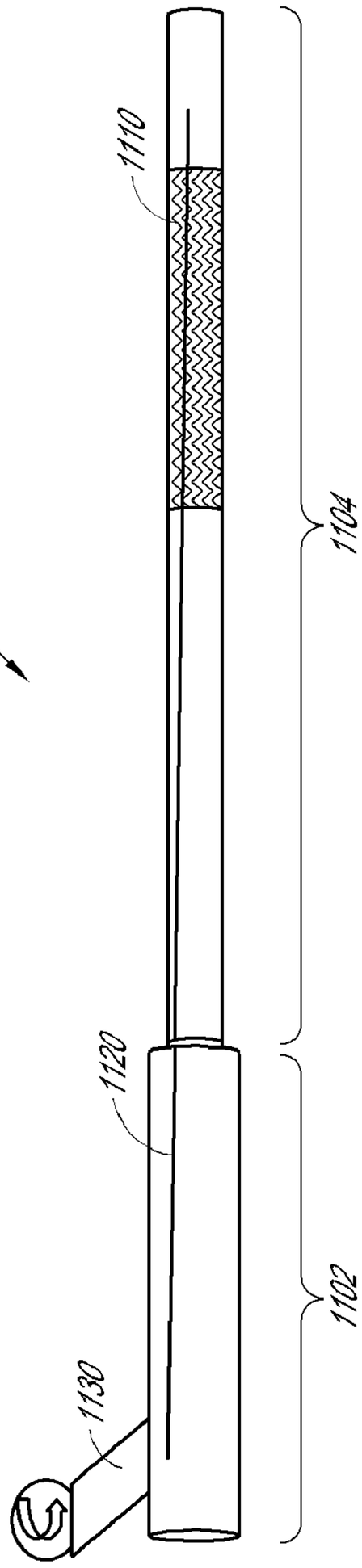

FIG. 25A

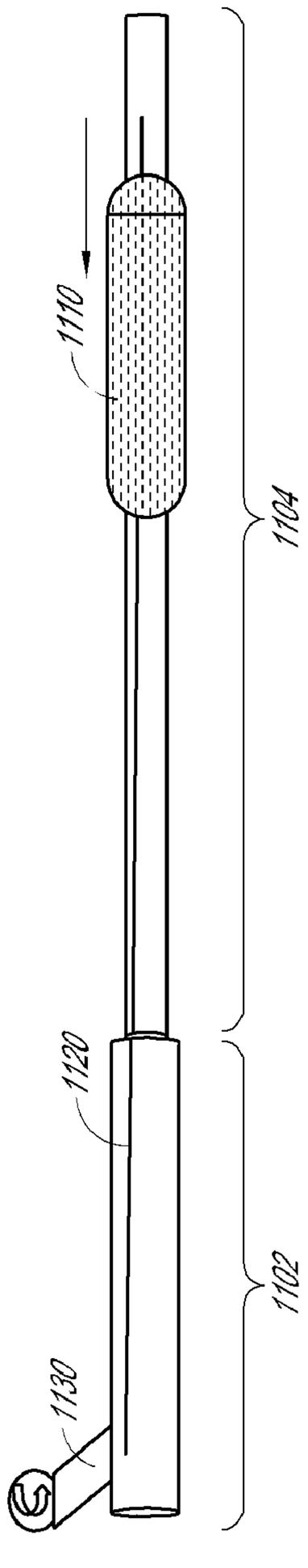

FIG. 25B

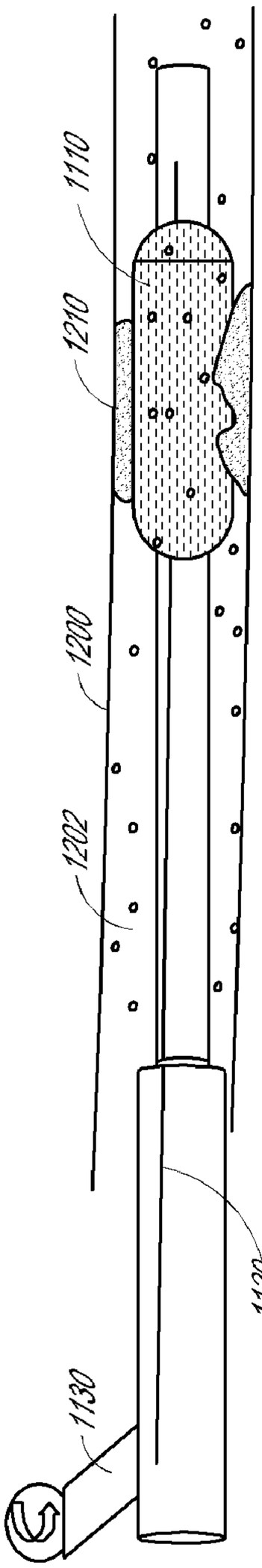

FIG. 26A

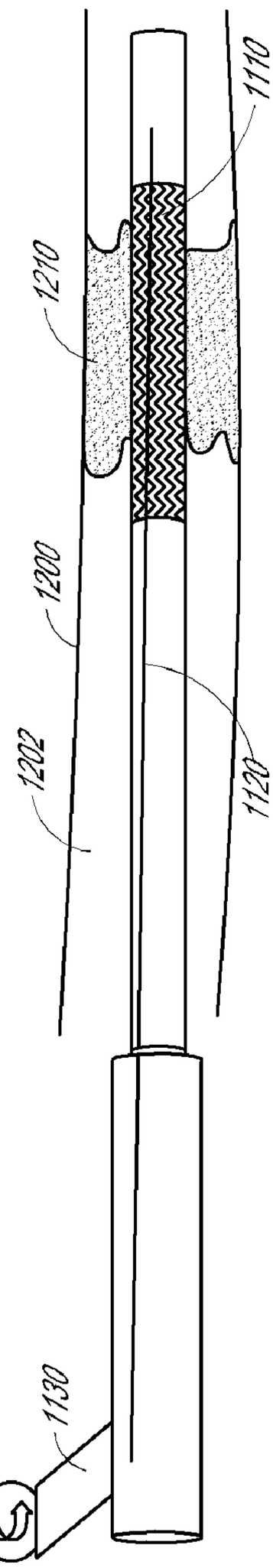

FIG. 26B

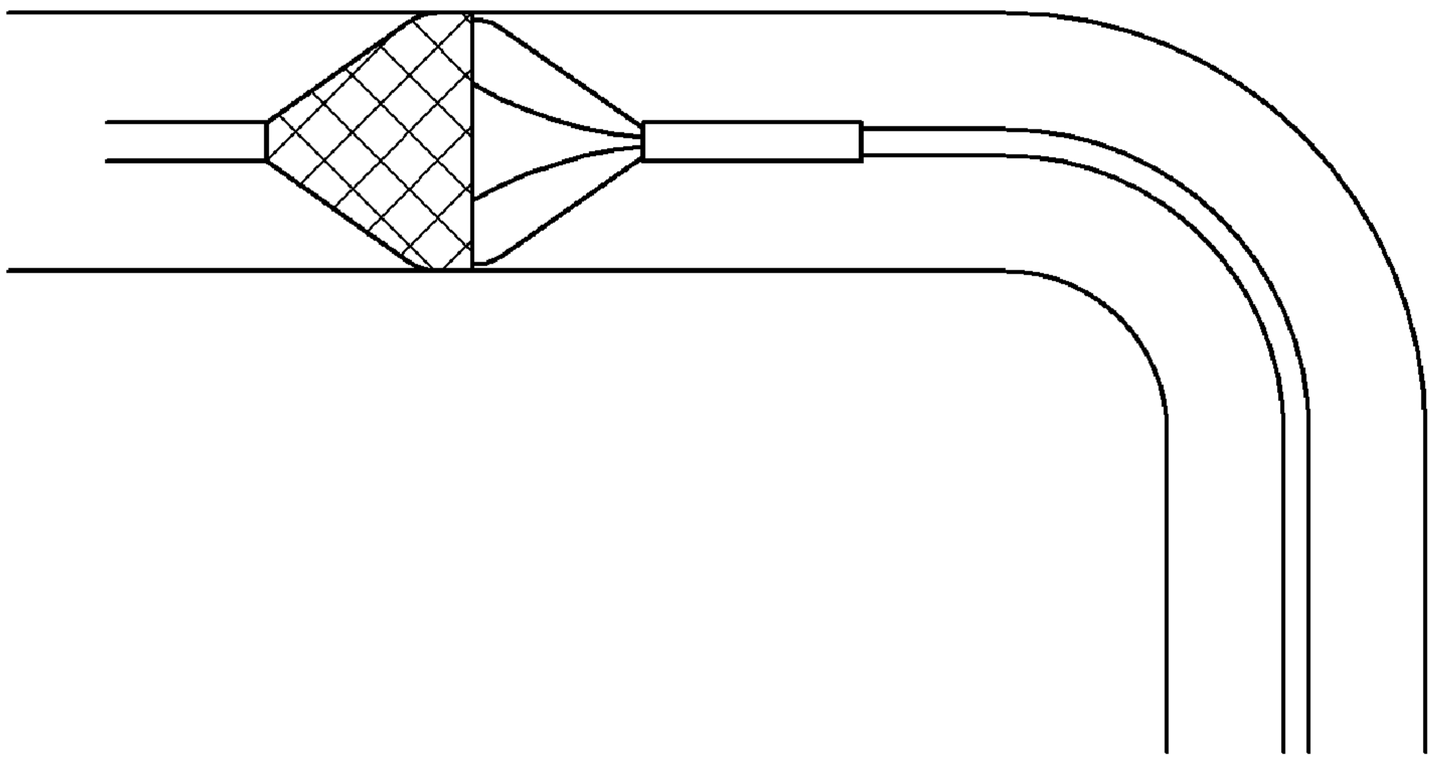

FIG. 27A

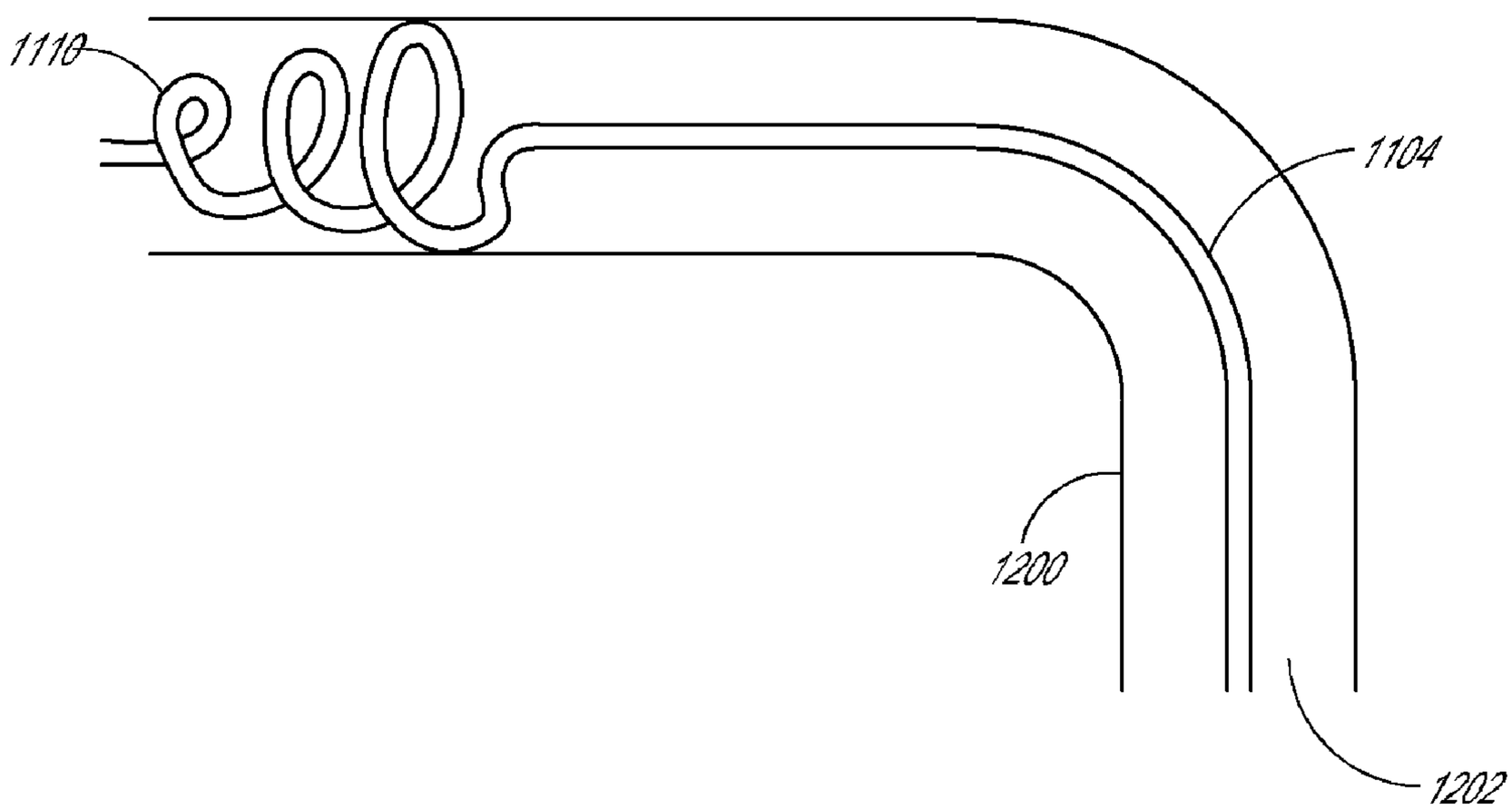

FIG. 27B

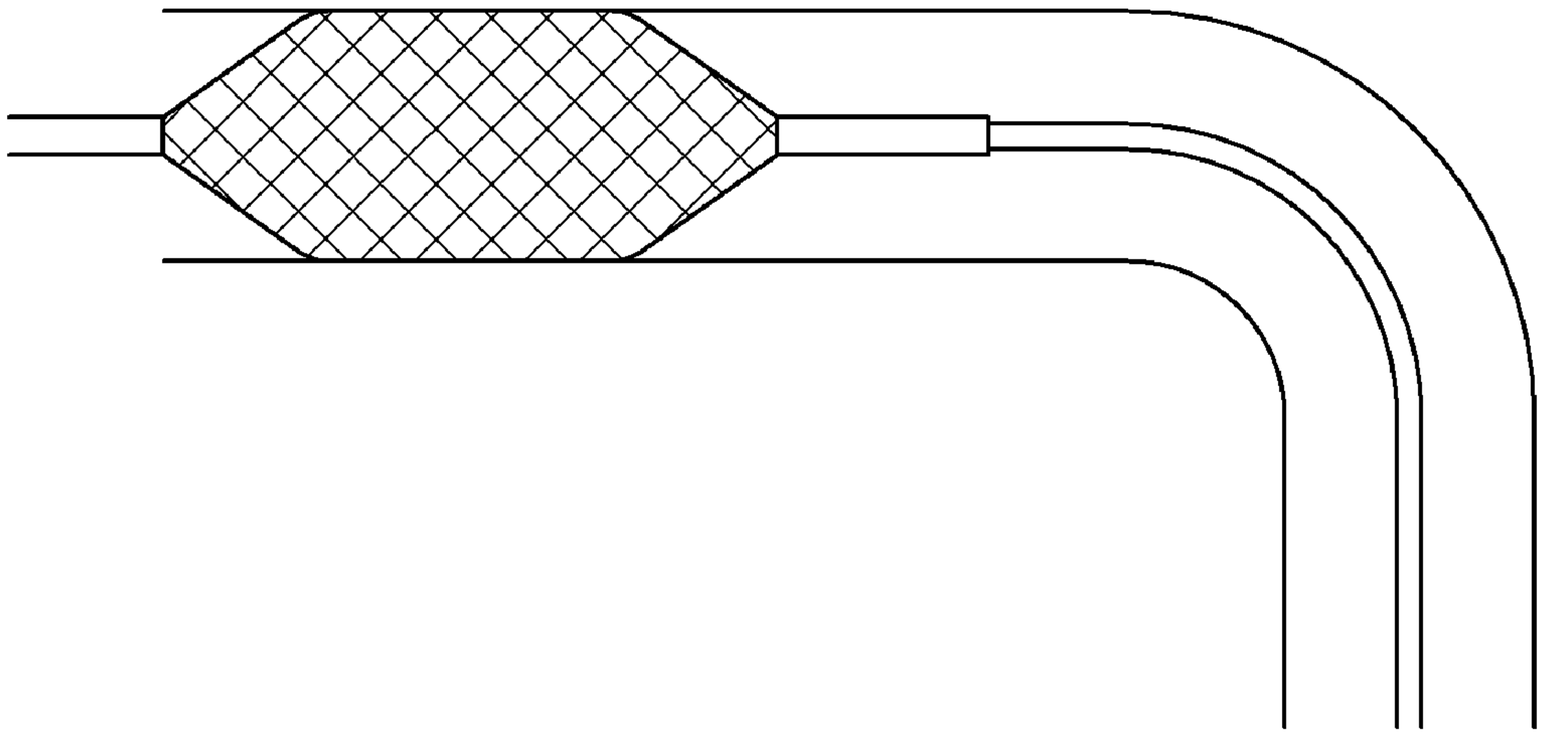

FIG. 28A

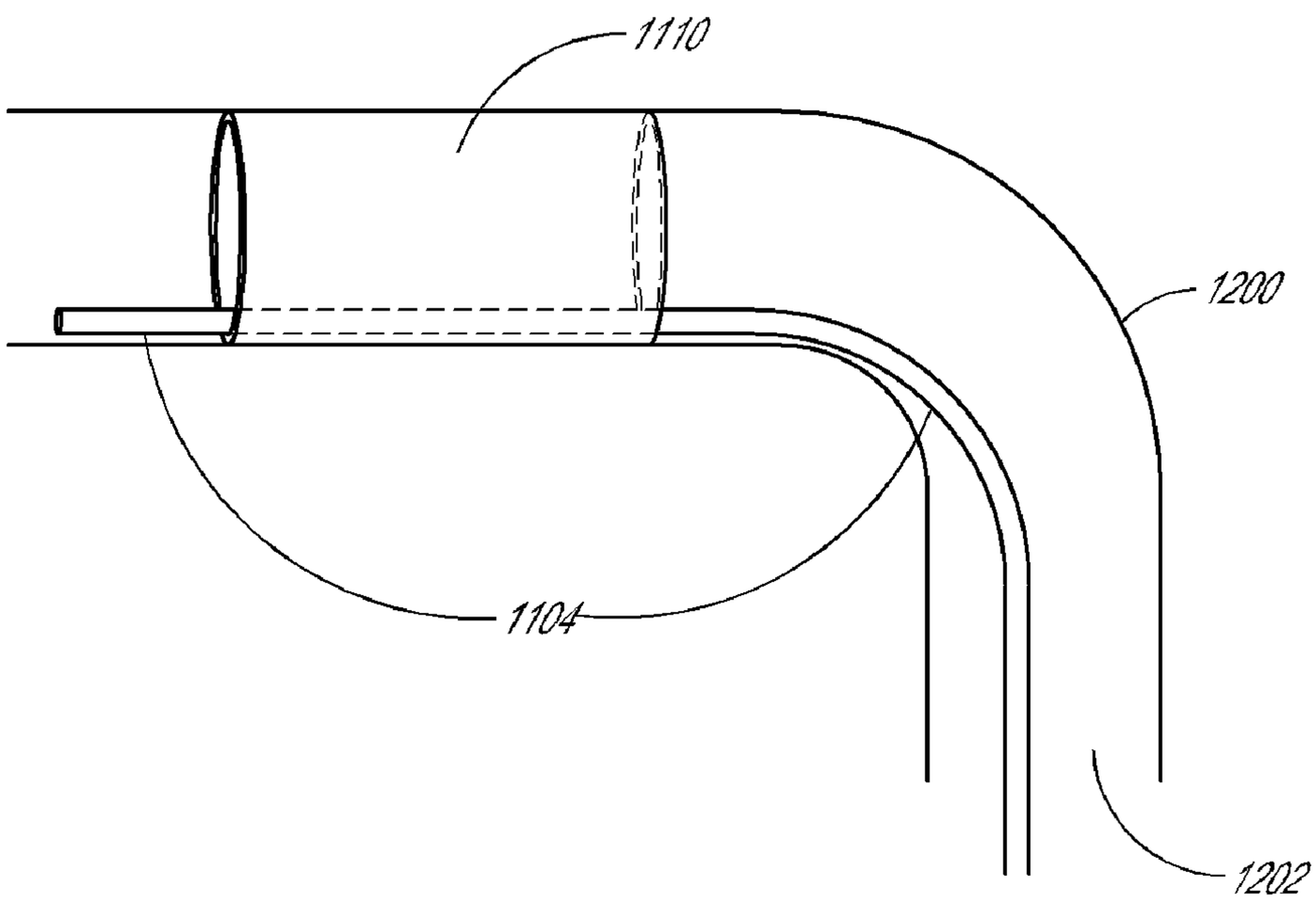

FIG. 28B

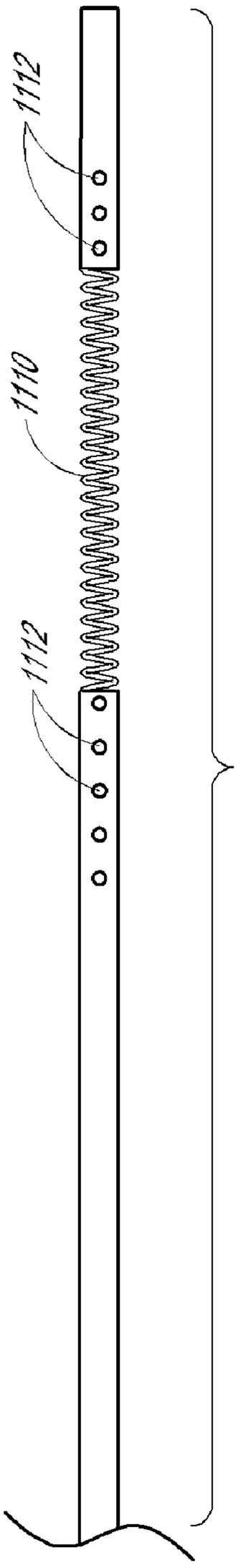

FIG. 29A

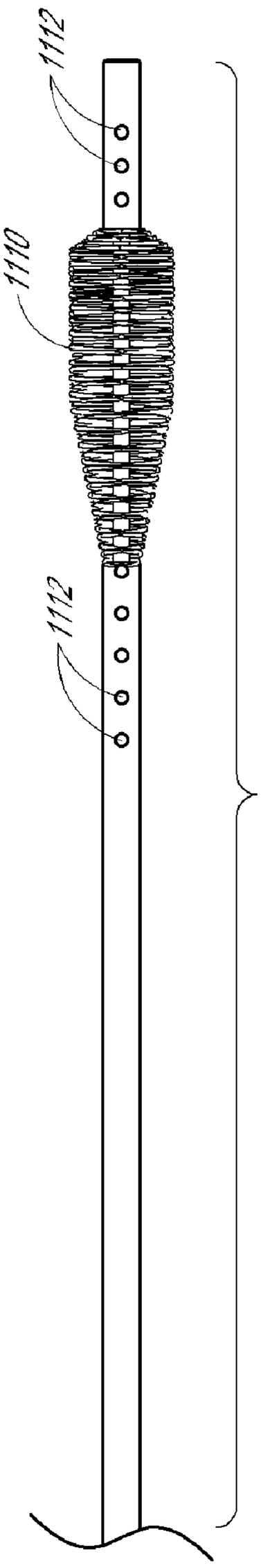

FIG. 29B

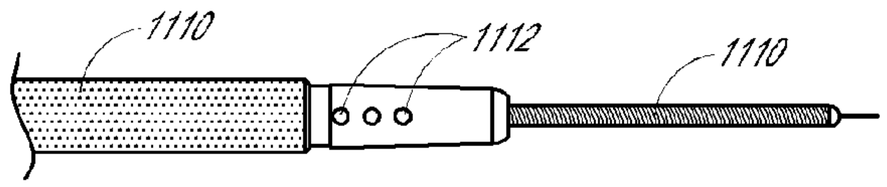

FIG. 30B

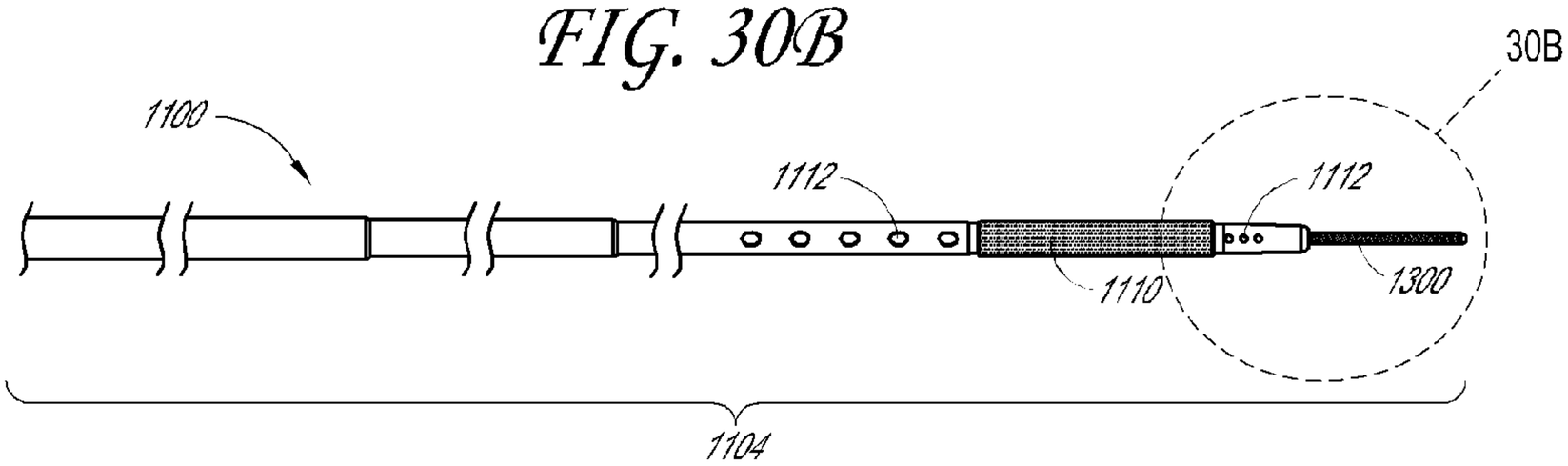

FIG. 30A

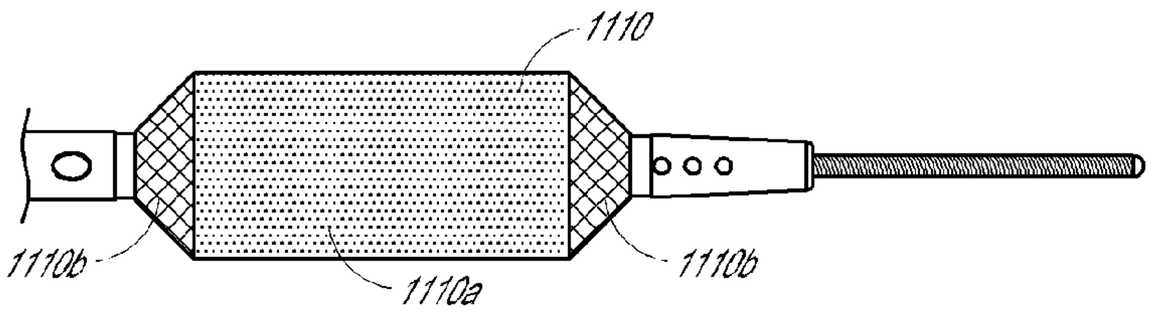

FIG. 30D

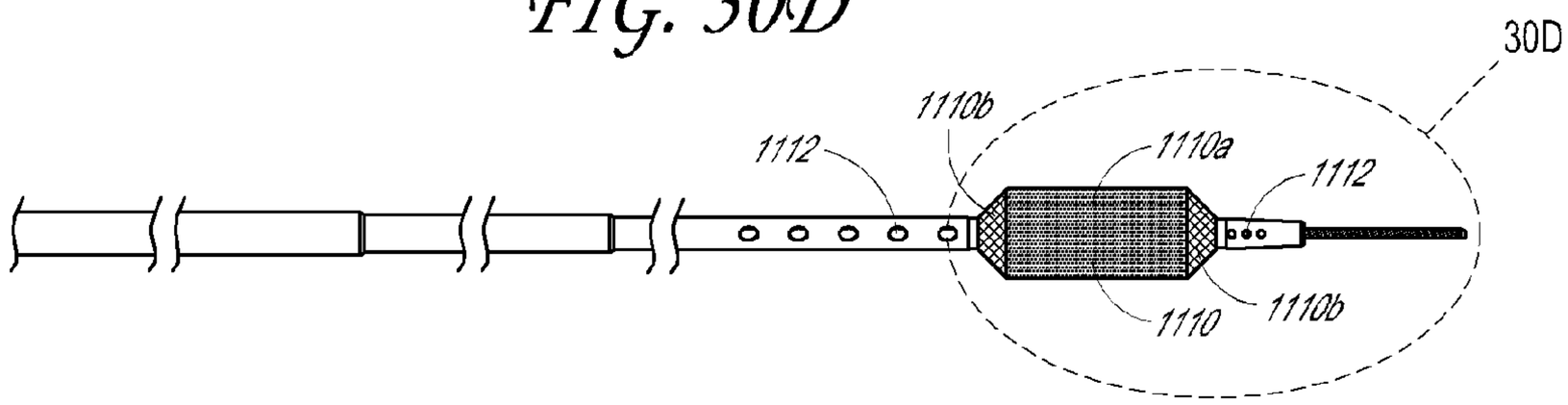

FIG. 30C

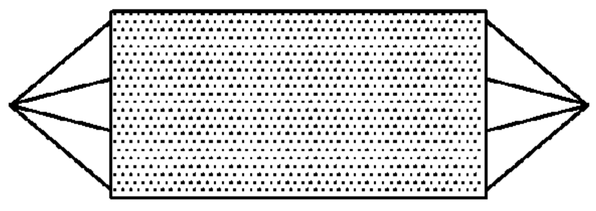

FIG. 30E

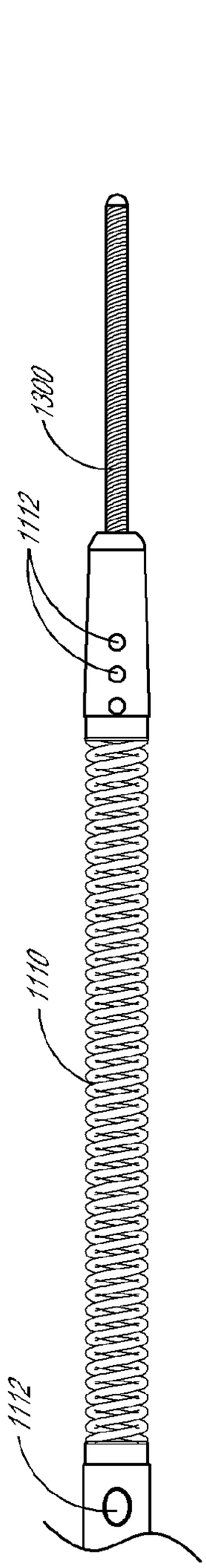

FIG. 31B

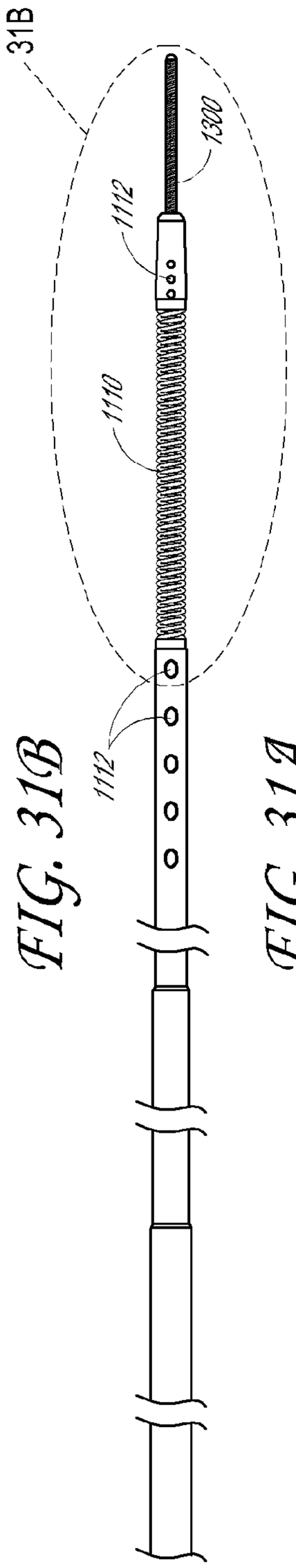

FIG. 31A

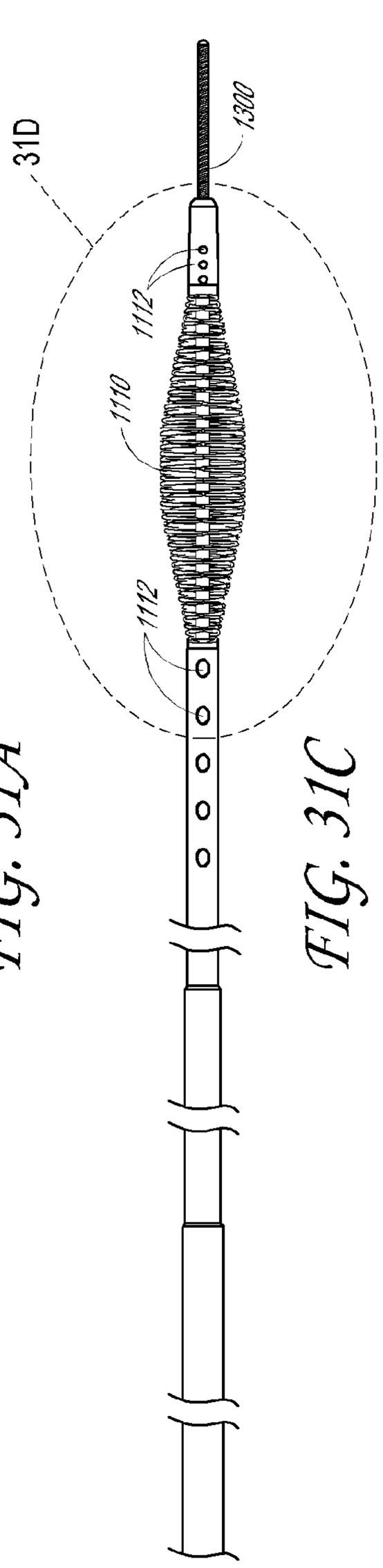

FIG. 31C

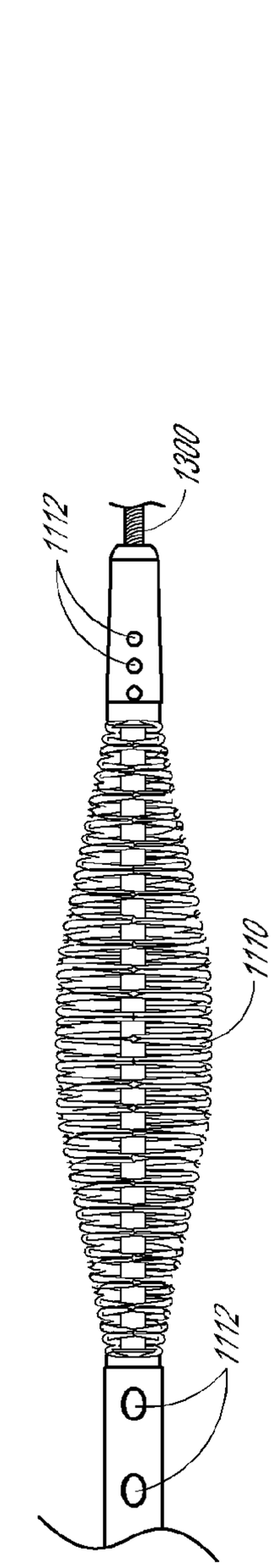

FIG. 31D

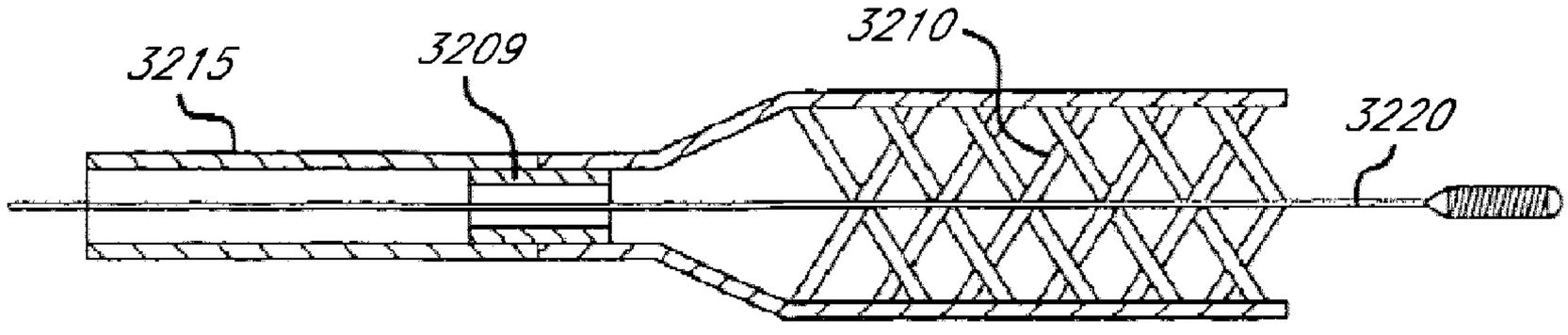

FIG. 32

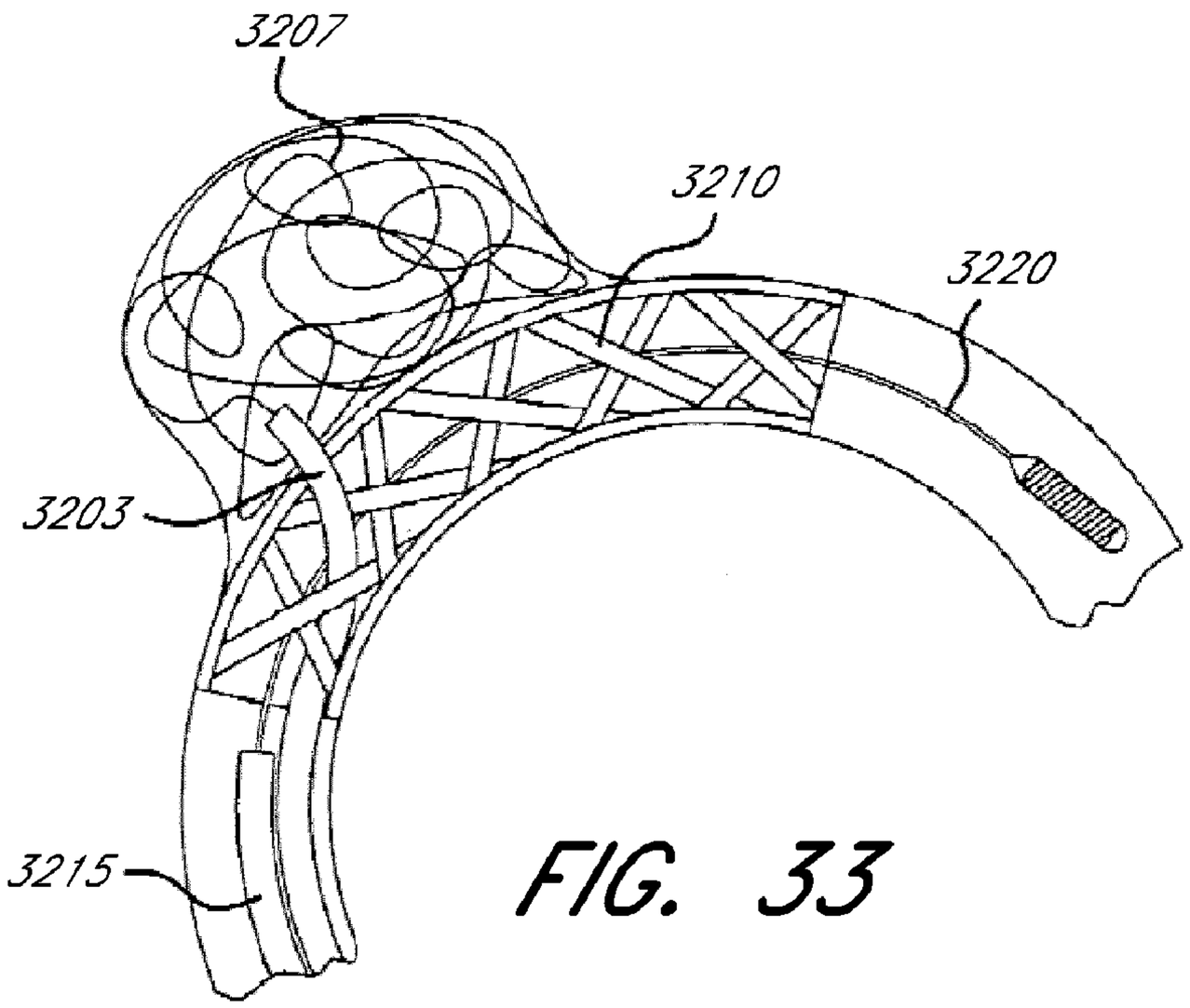

FIG. 33

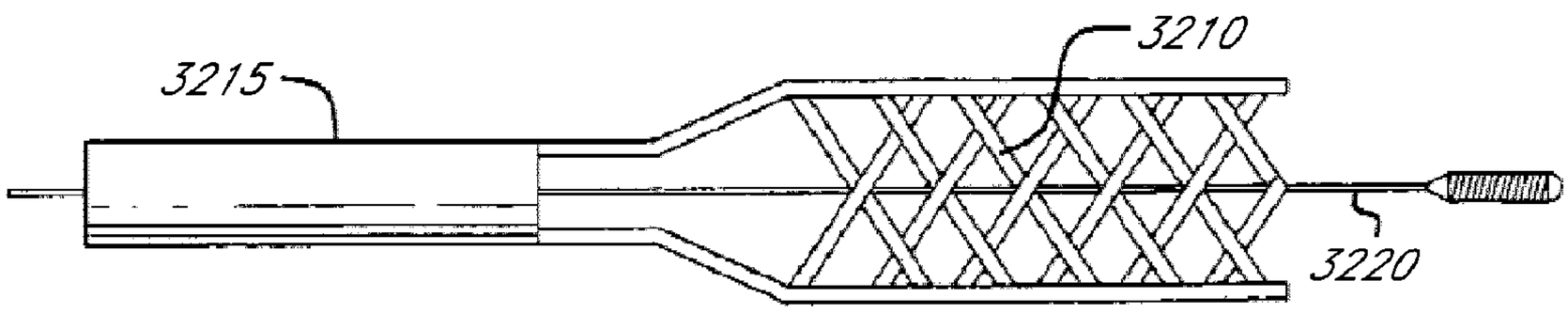

FIG. 34

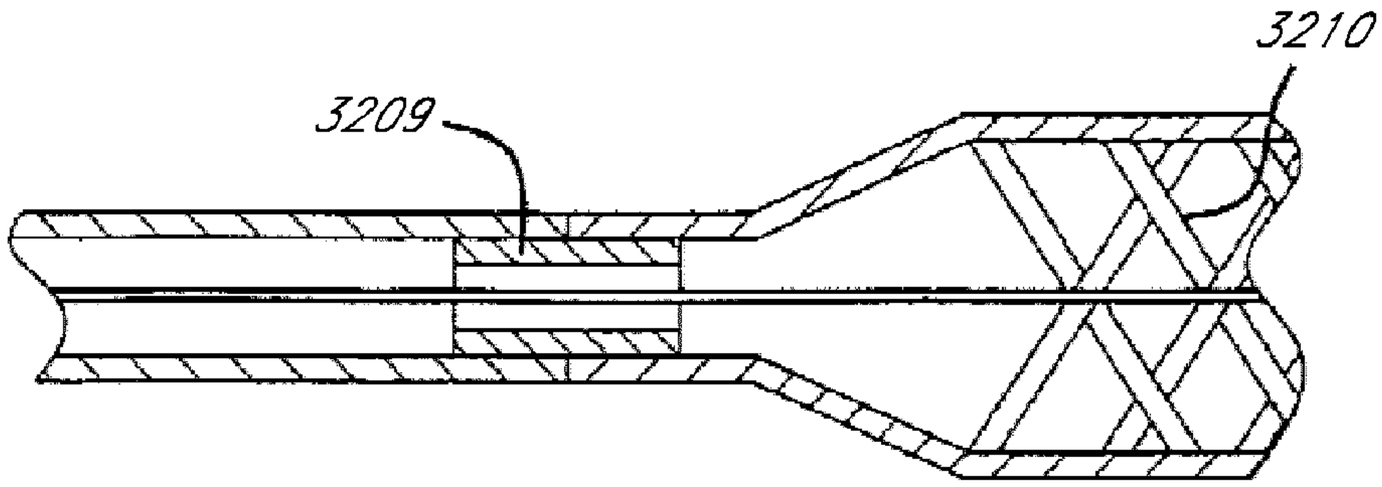

FIG. 35

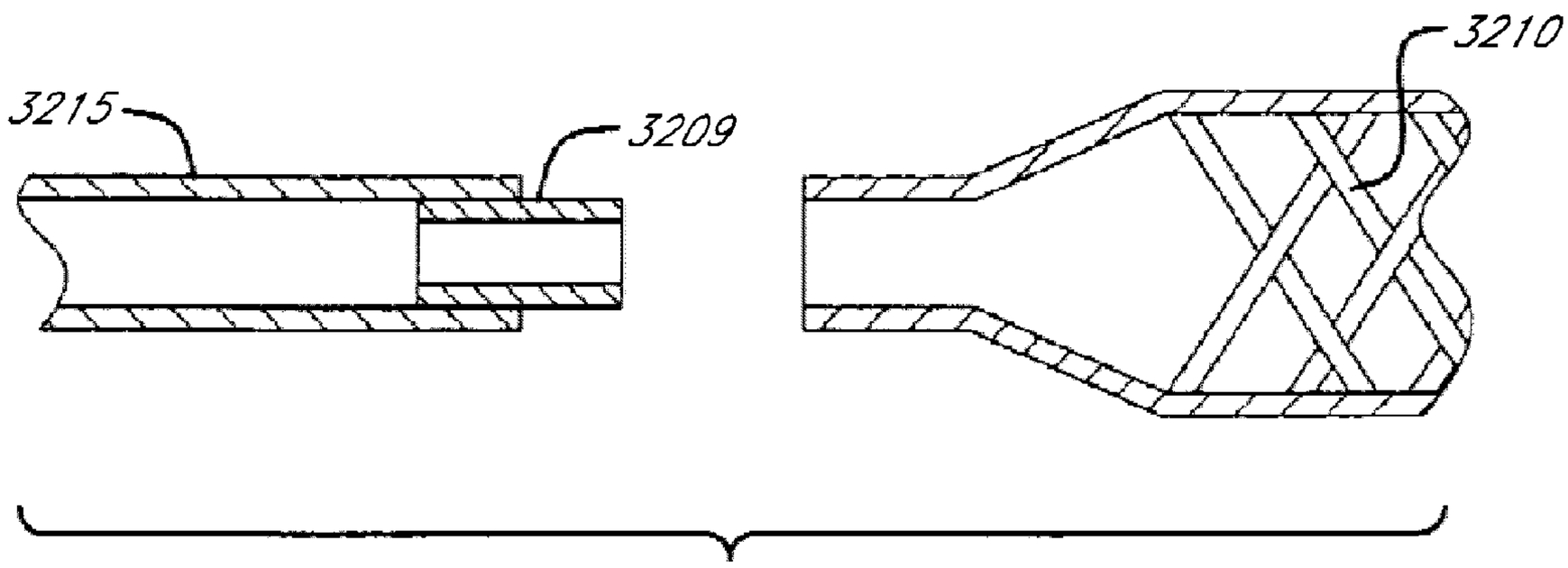

FIG. 36

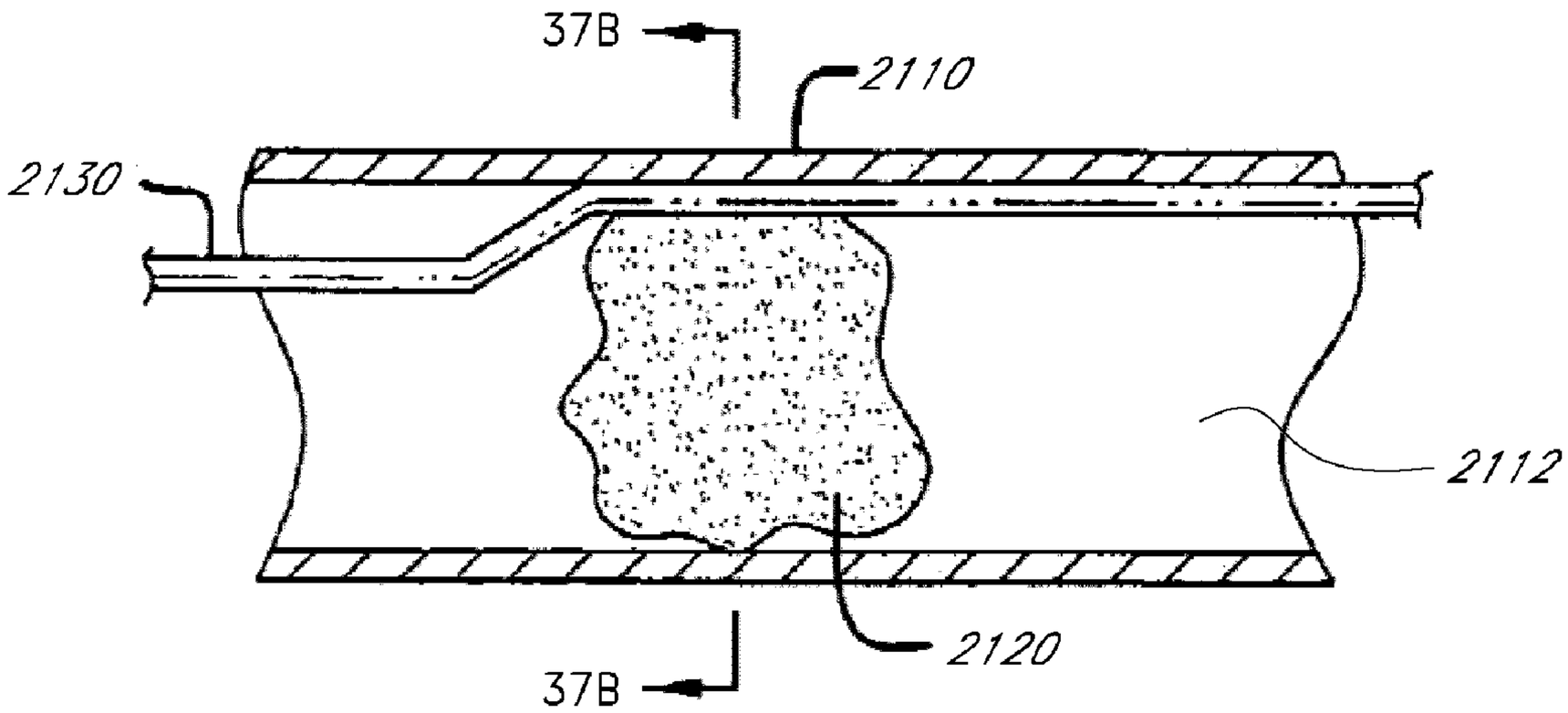

FIG. 37A

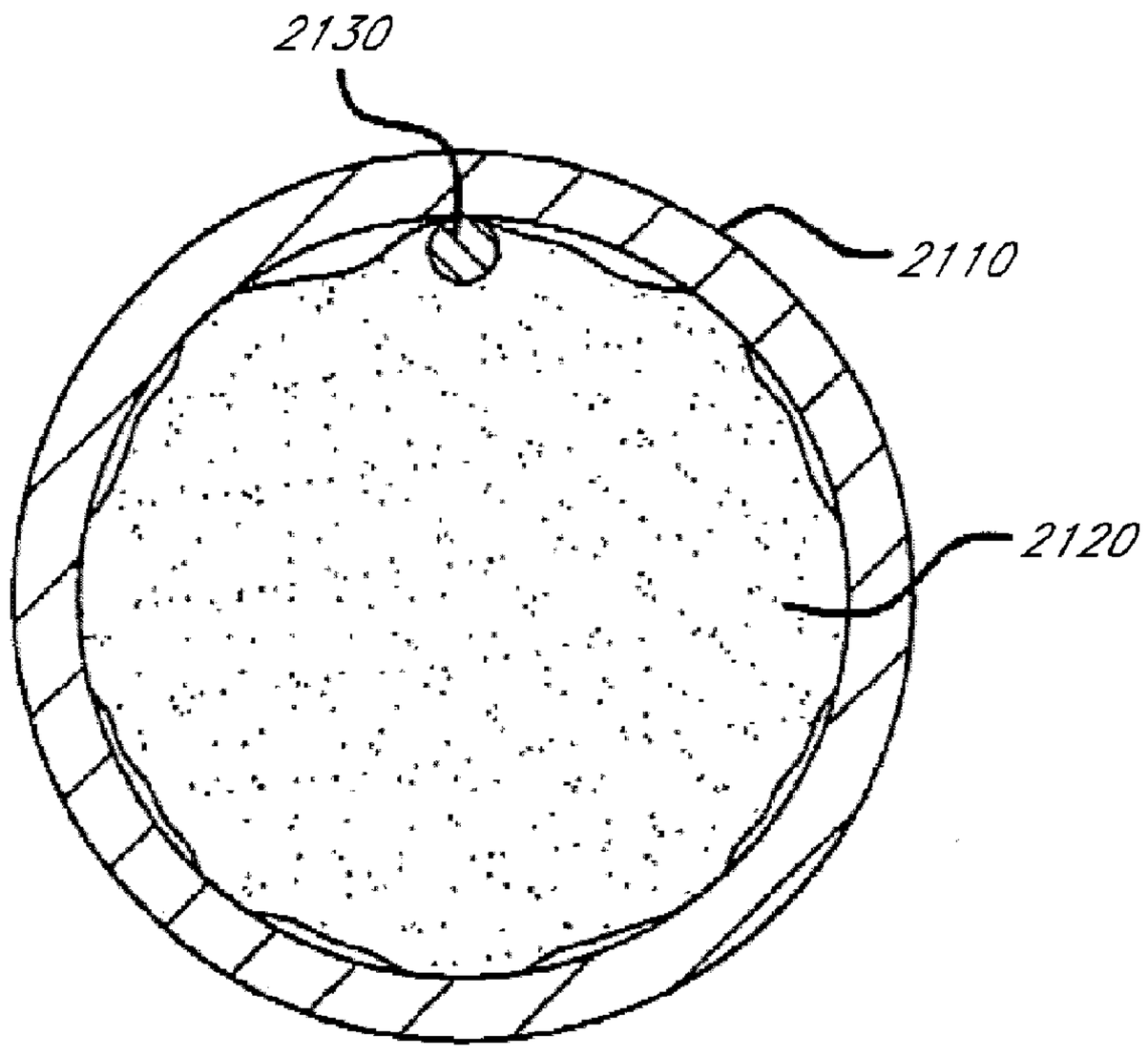

FIG. 37B

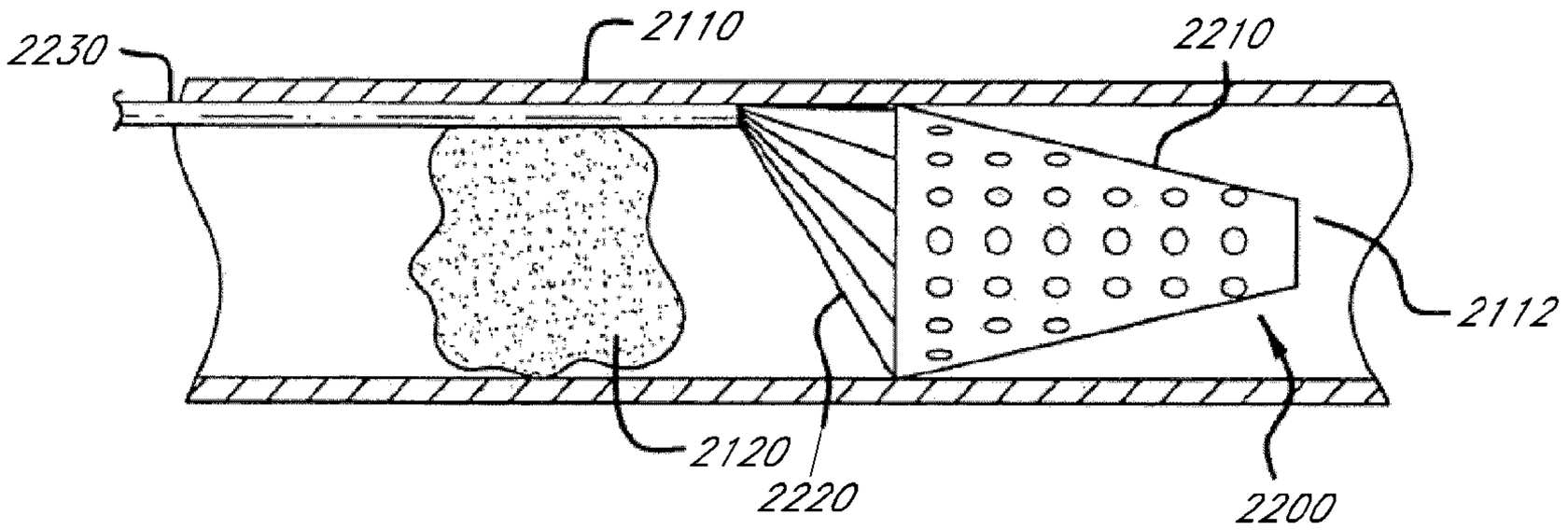
2230
2110
2210
2112
2120
2220
2200

FIG. 38

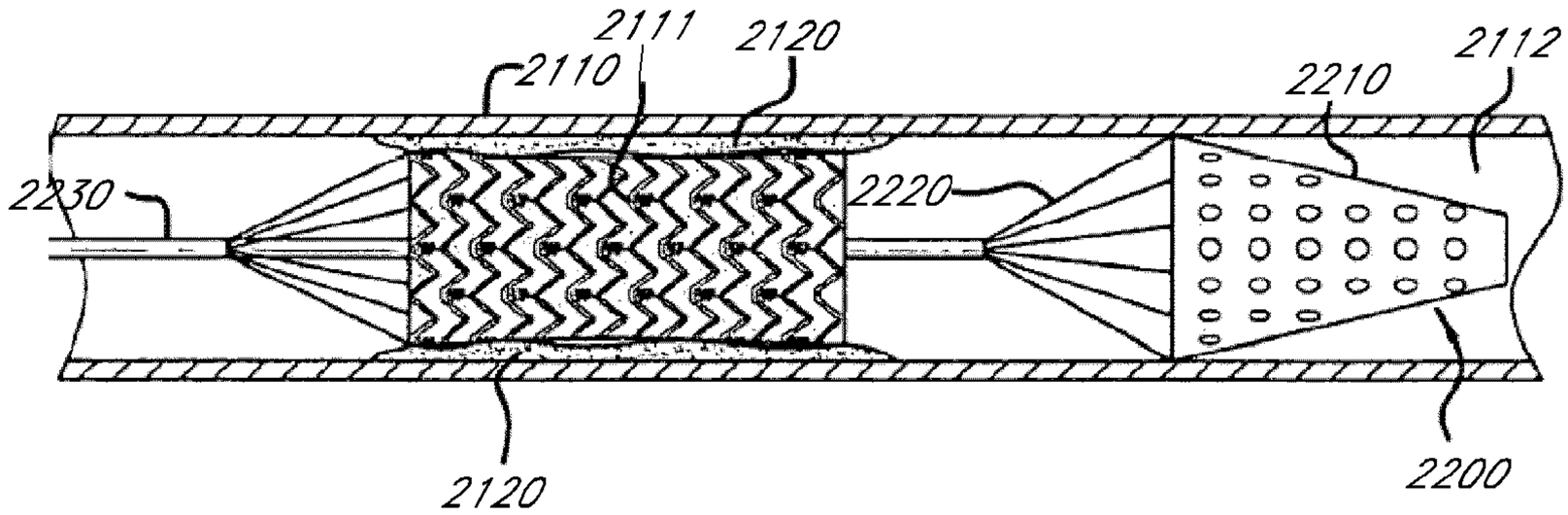
2111
2120
2110
2112
2210
2230
2220
2120
2200

FIG. 39

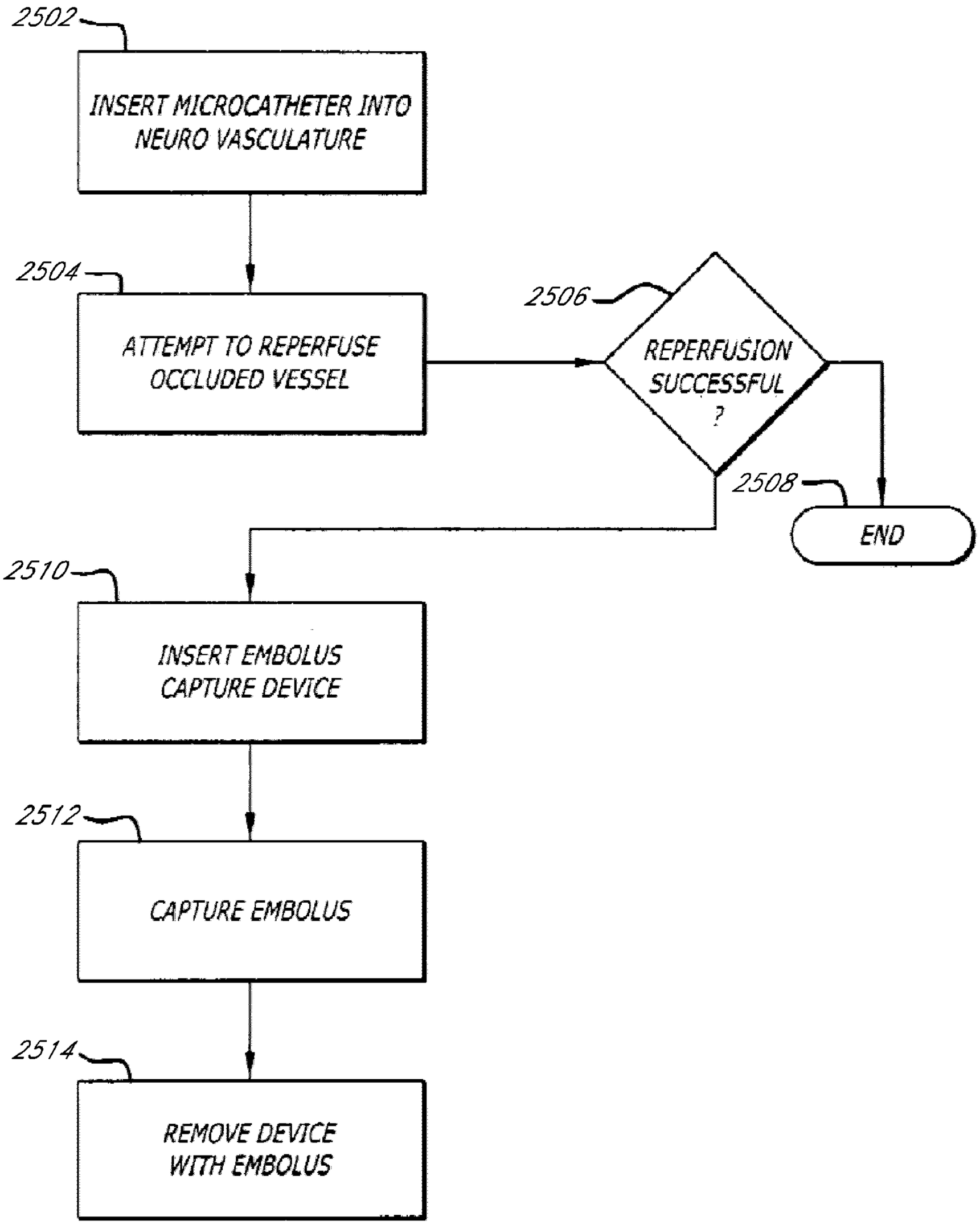
2502
INSERT MICROCATHETER INTO NEURO VASCULATURE
2504
ATTEMPT TO REPERFUSE OCCLUDED VESSEL
2506
REPERFUSION SUCCESSFUL ?
2508
END
2510
INSERT EMBOLUS CAPTURE DEVICE
2512
CAPTURE EMBOLUS
2514
REMOVE DEVICE WITH EMBOLUS

FIG. 40

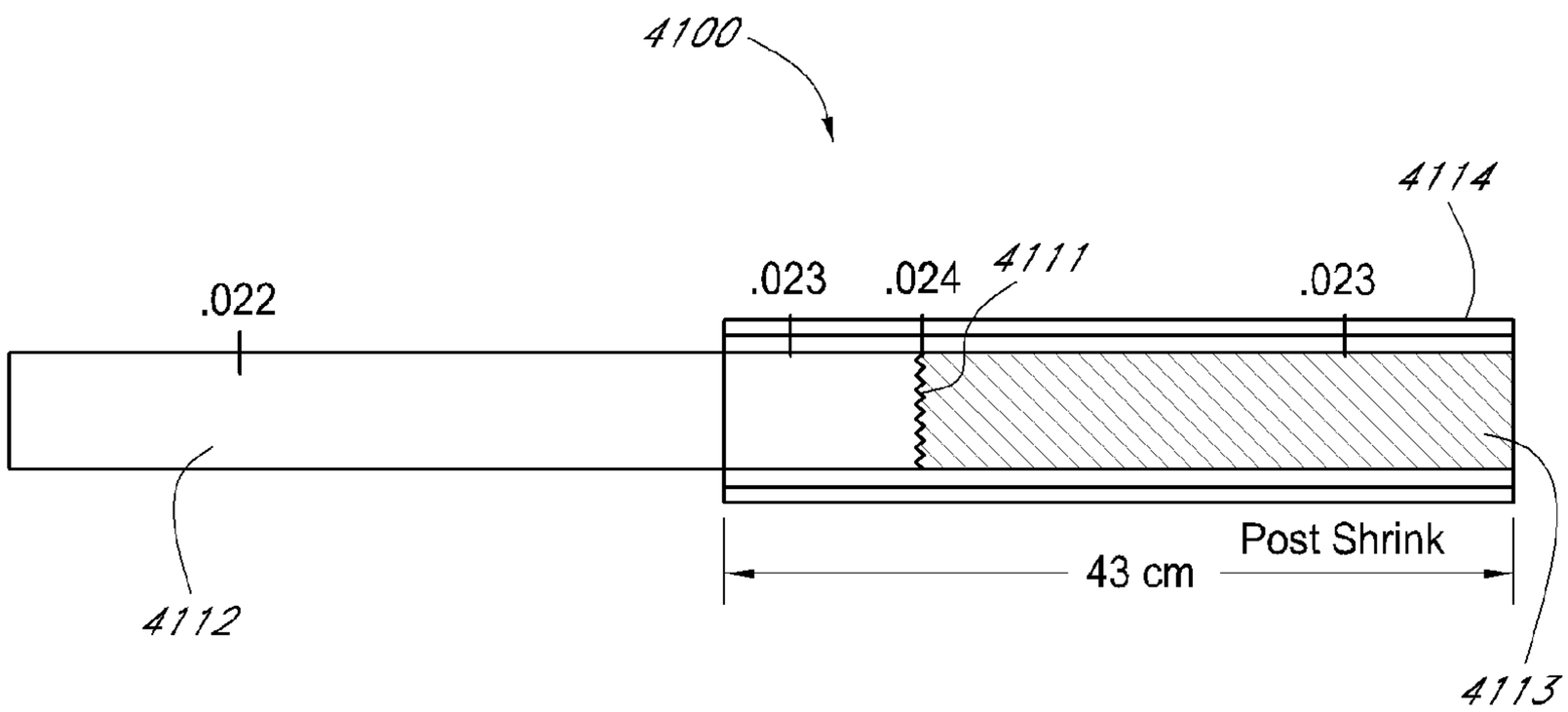
4100
4114
4111
.022
.023
.024
.023
Post Shrink
43 cm
4112
4113

FIG. 41

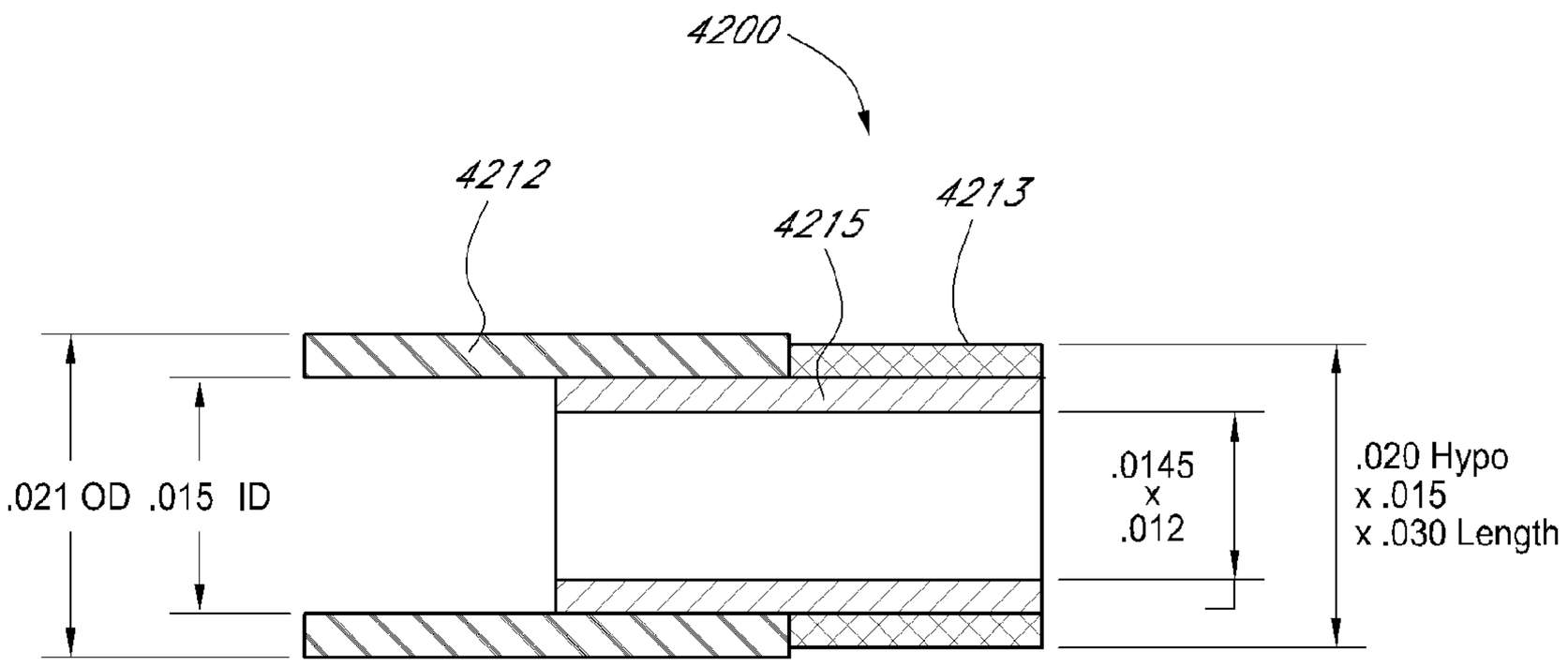
4200
4212
4215
4213
.021 OD
.015 ID
.0145
x
.012
.020 Hypo
x .015
x .030 Length

FIG. 42

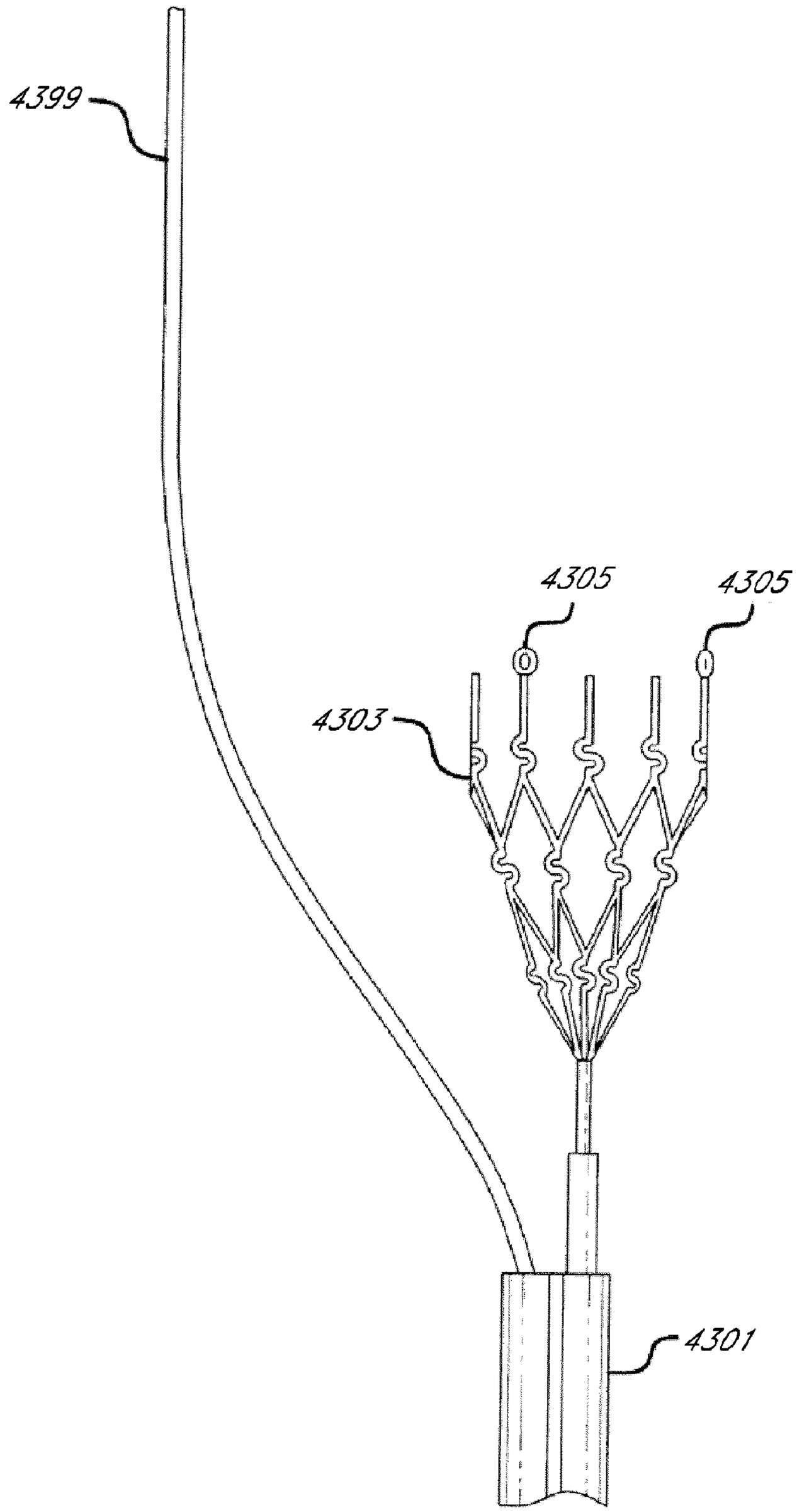

FIG. 43A

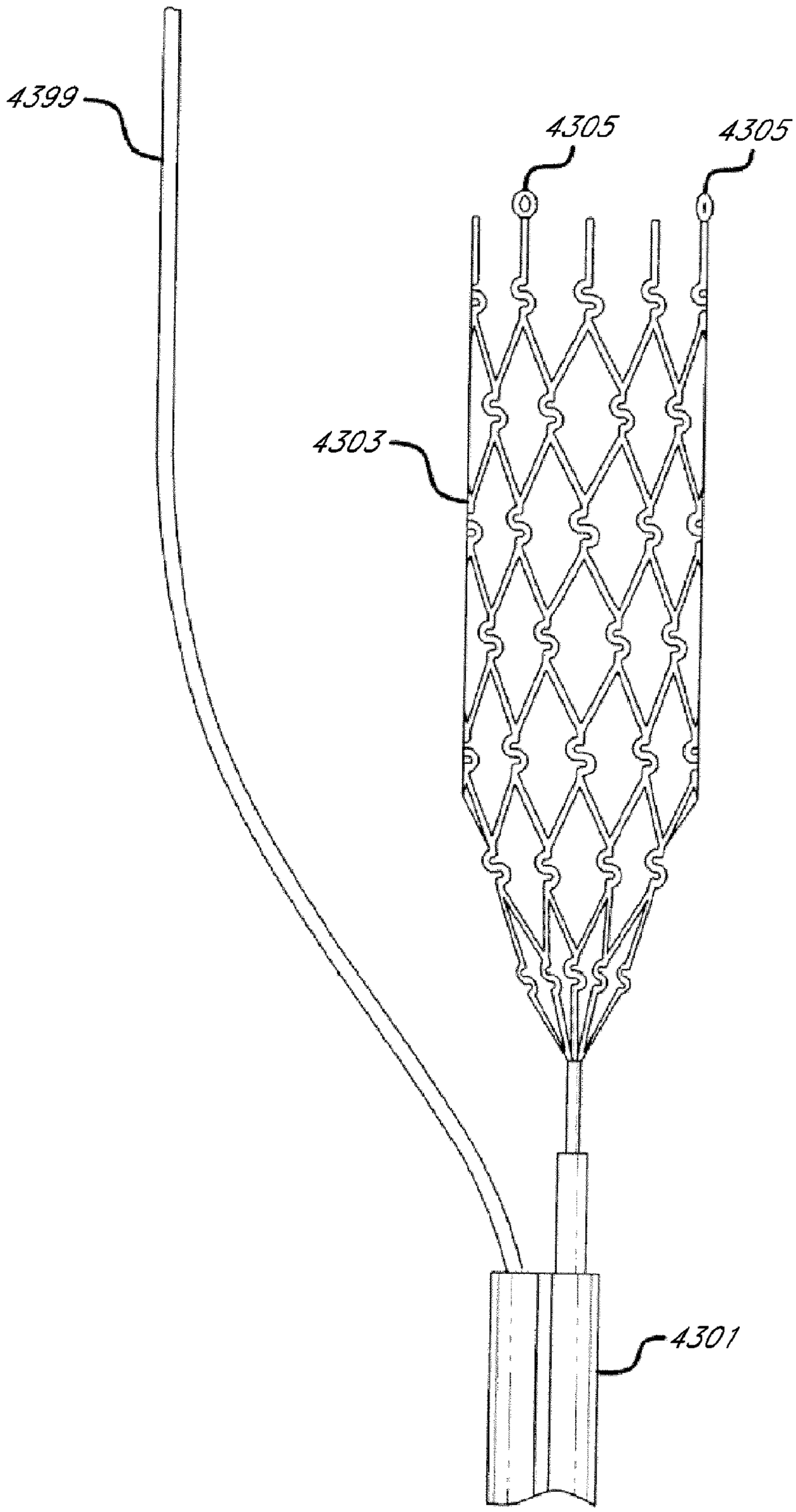

FIG.43B

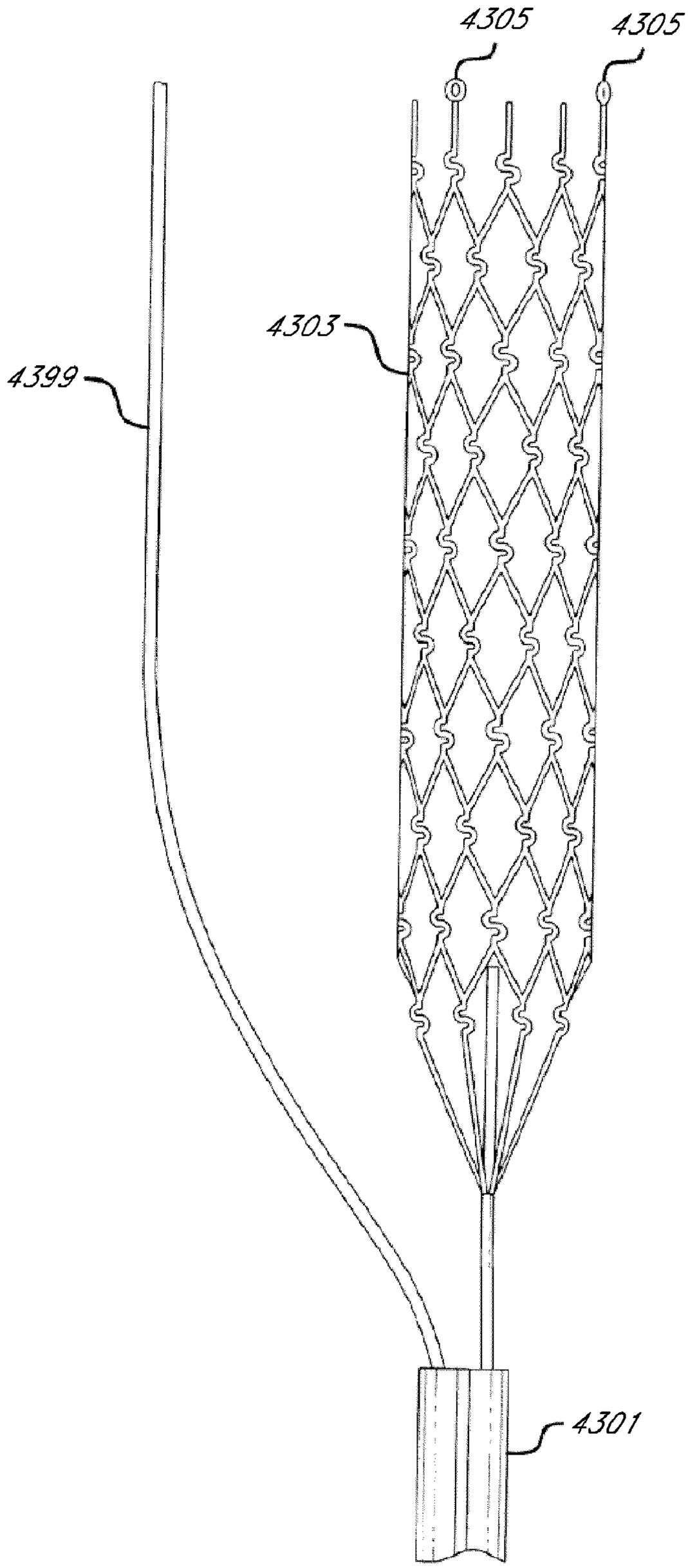

FIG. 43C

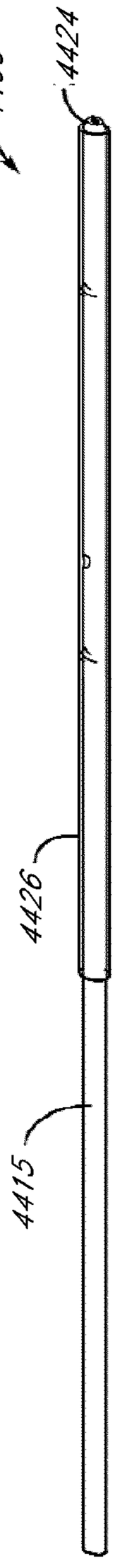

FIG. 44

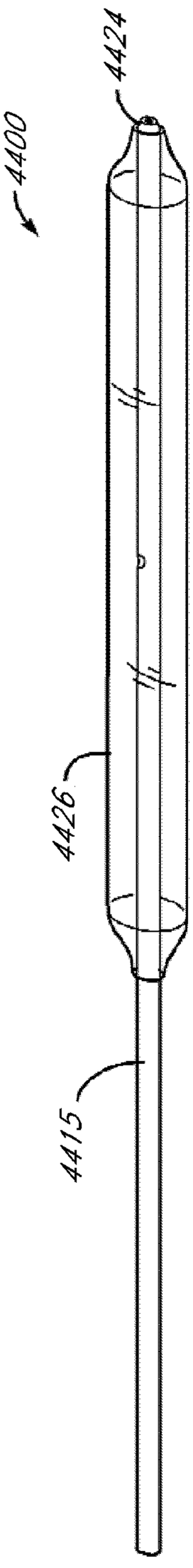

FIG. 45

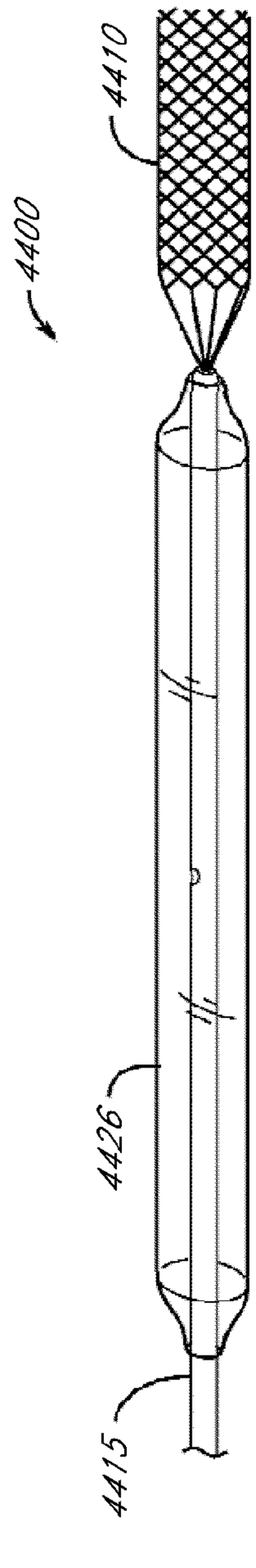

FIG. 46

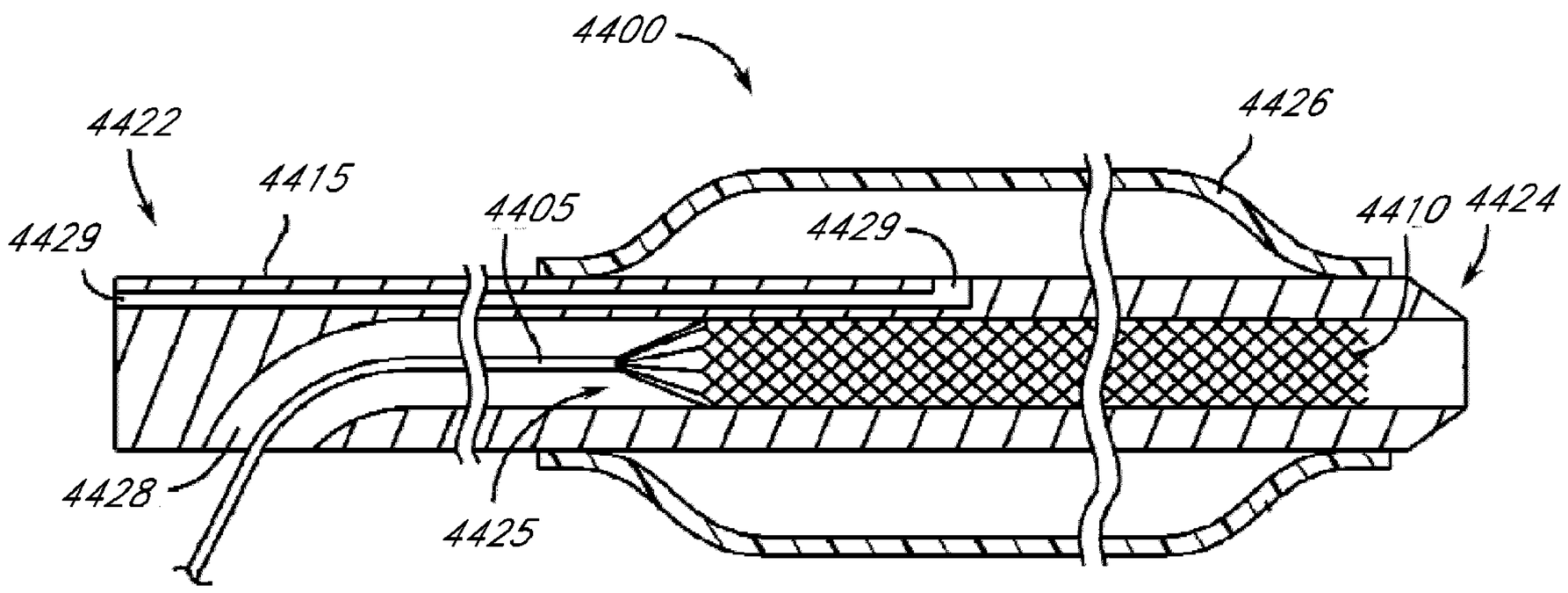
4400
4422
4415
4429
4405
4429
4426
4410
4424
4428
4425

FIG. 47

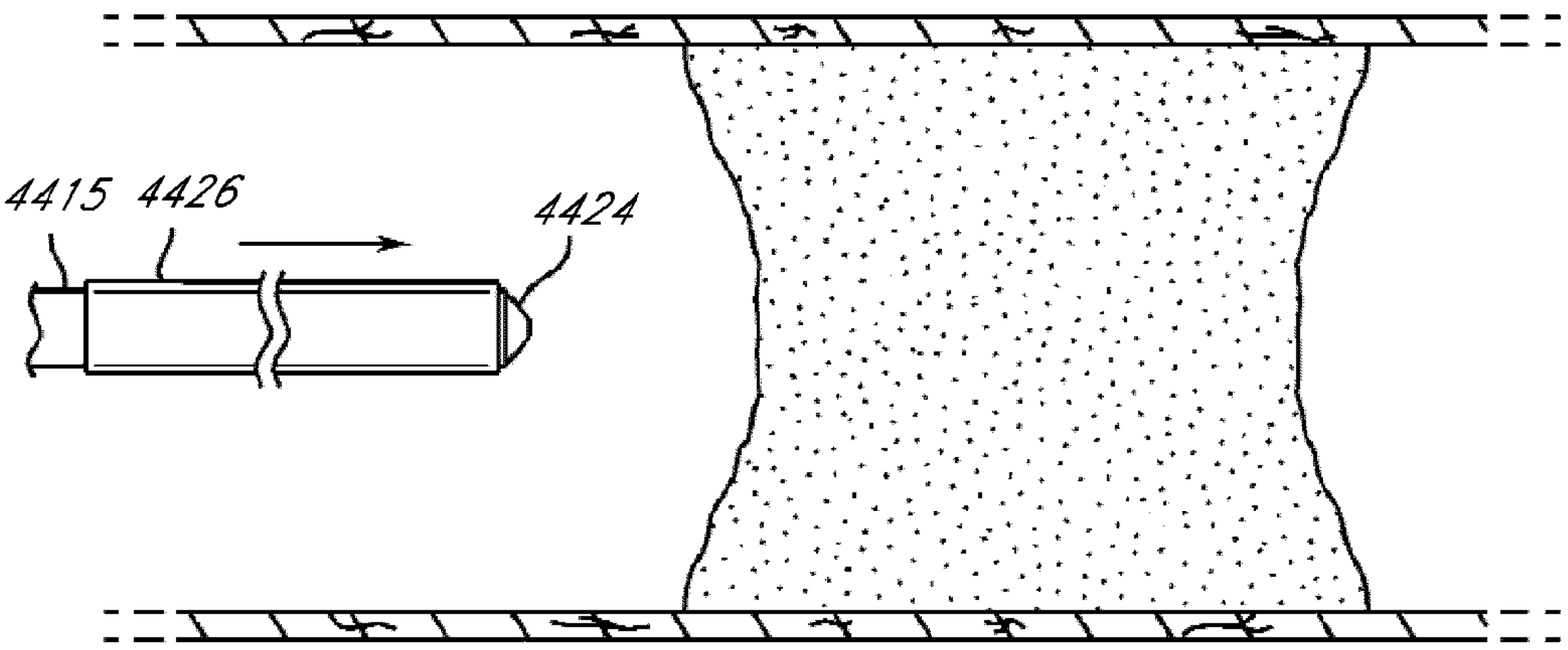
4415
4426
4424

FIG. 48

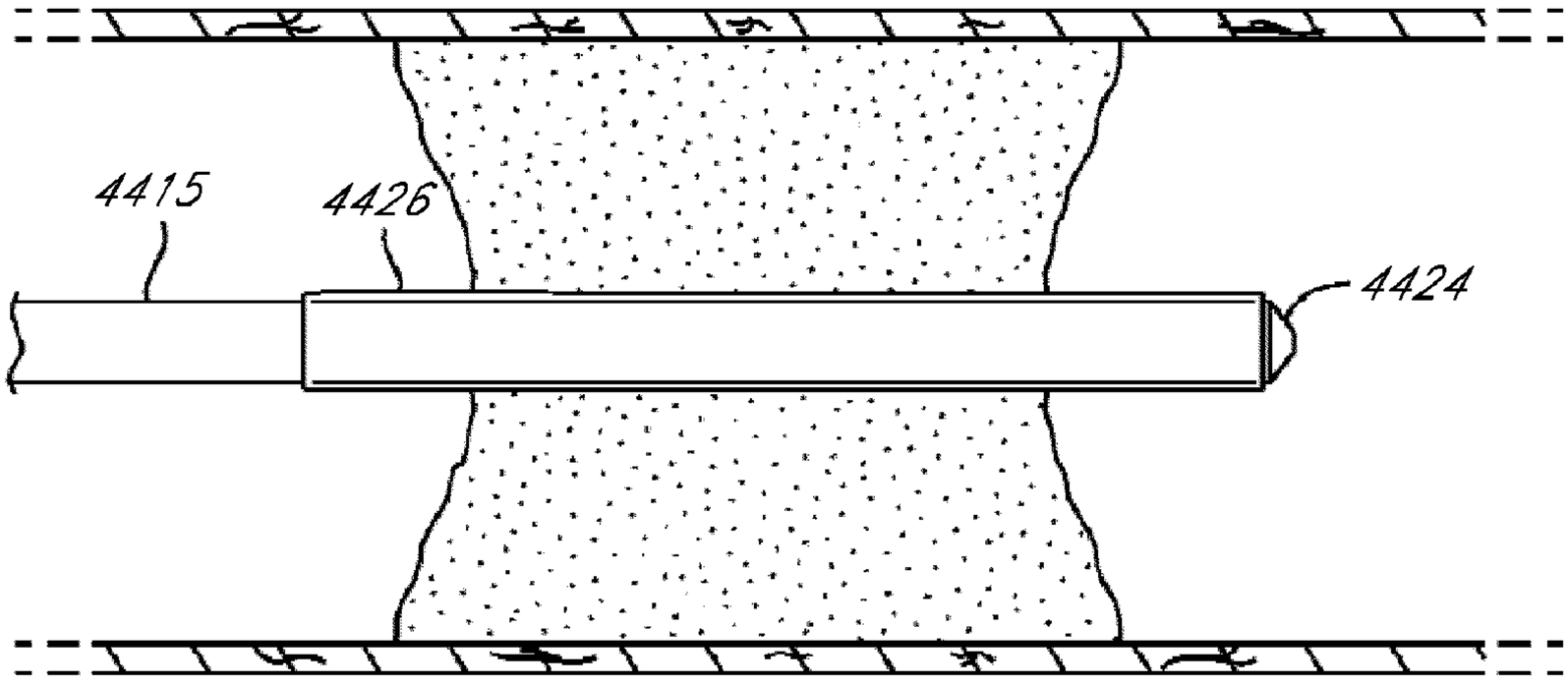

FIG. 49

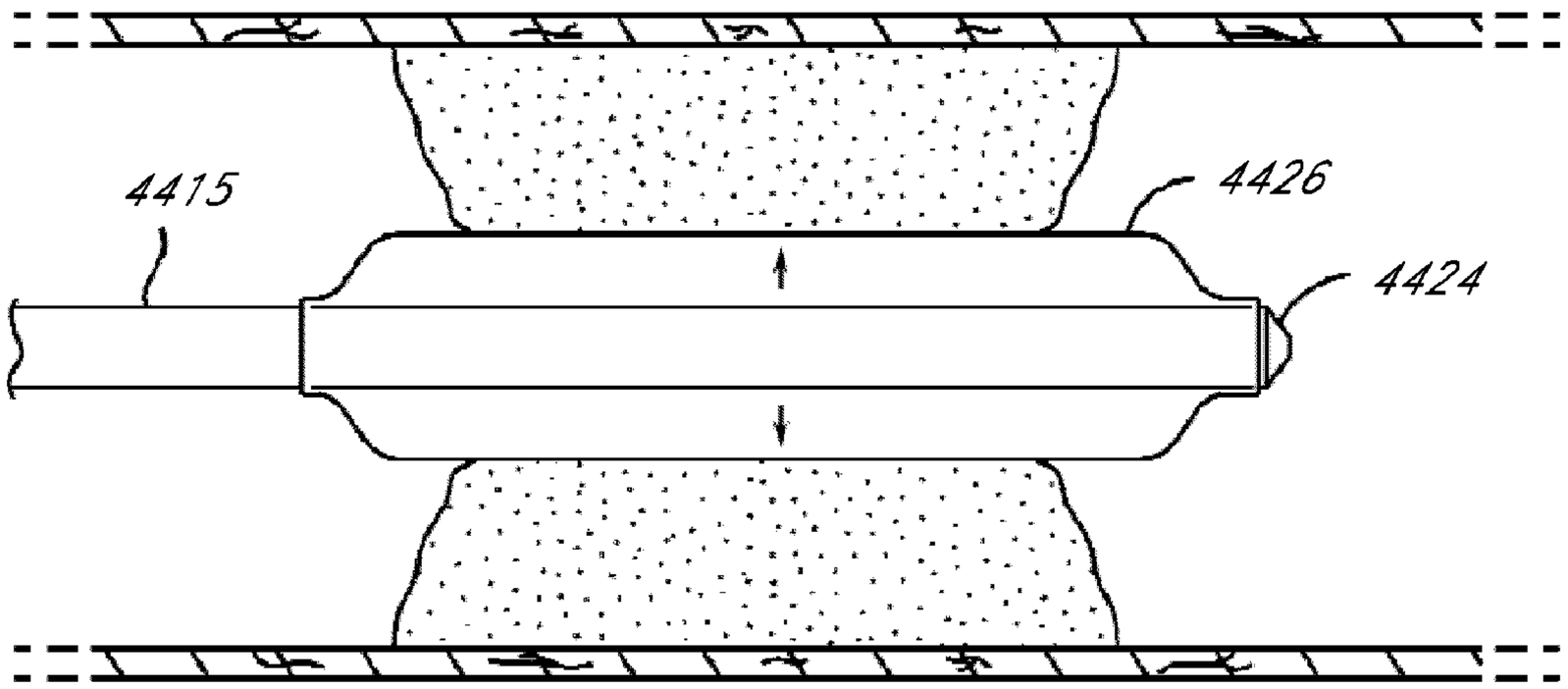

FIG. 50

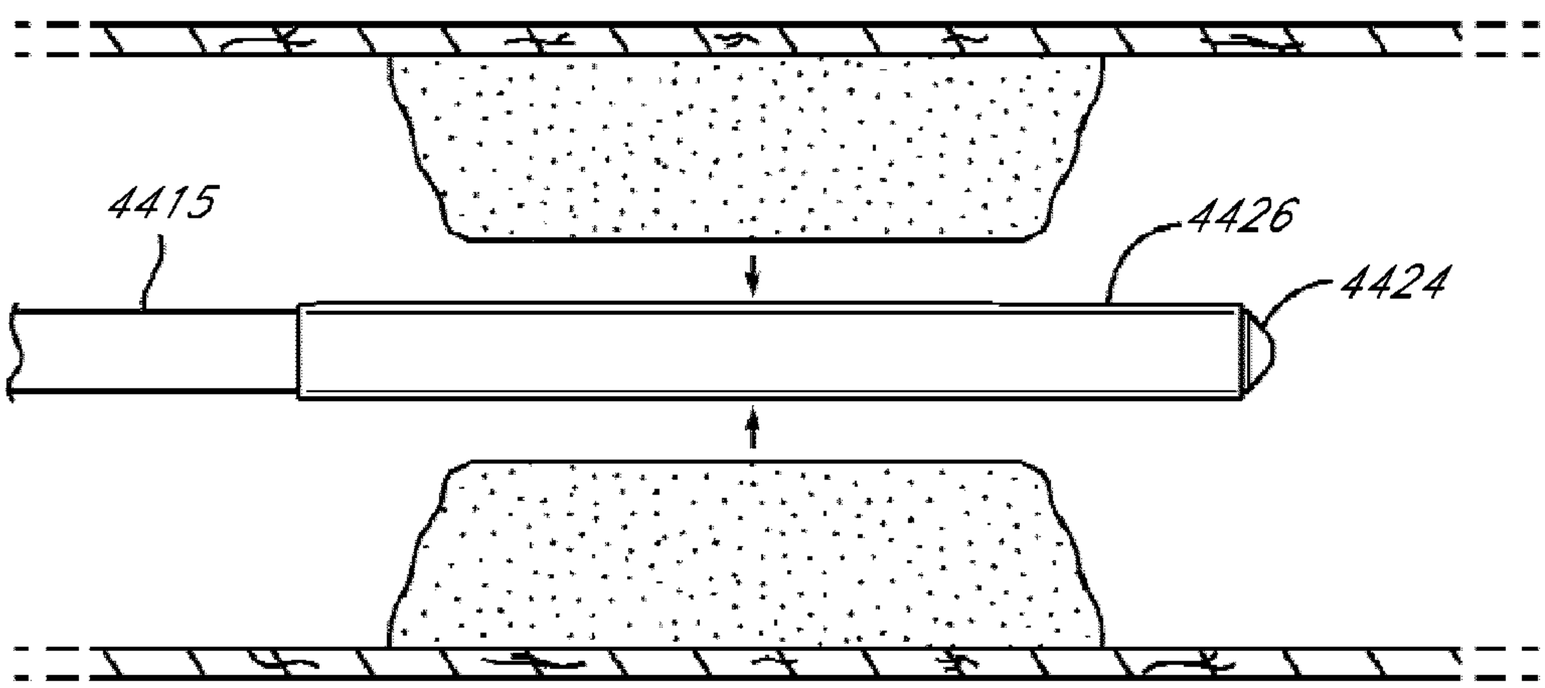

FIG. 51

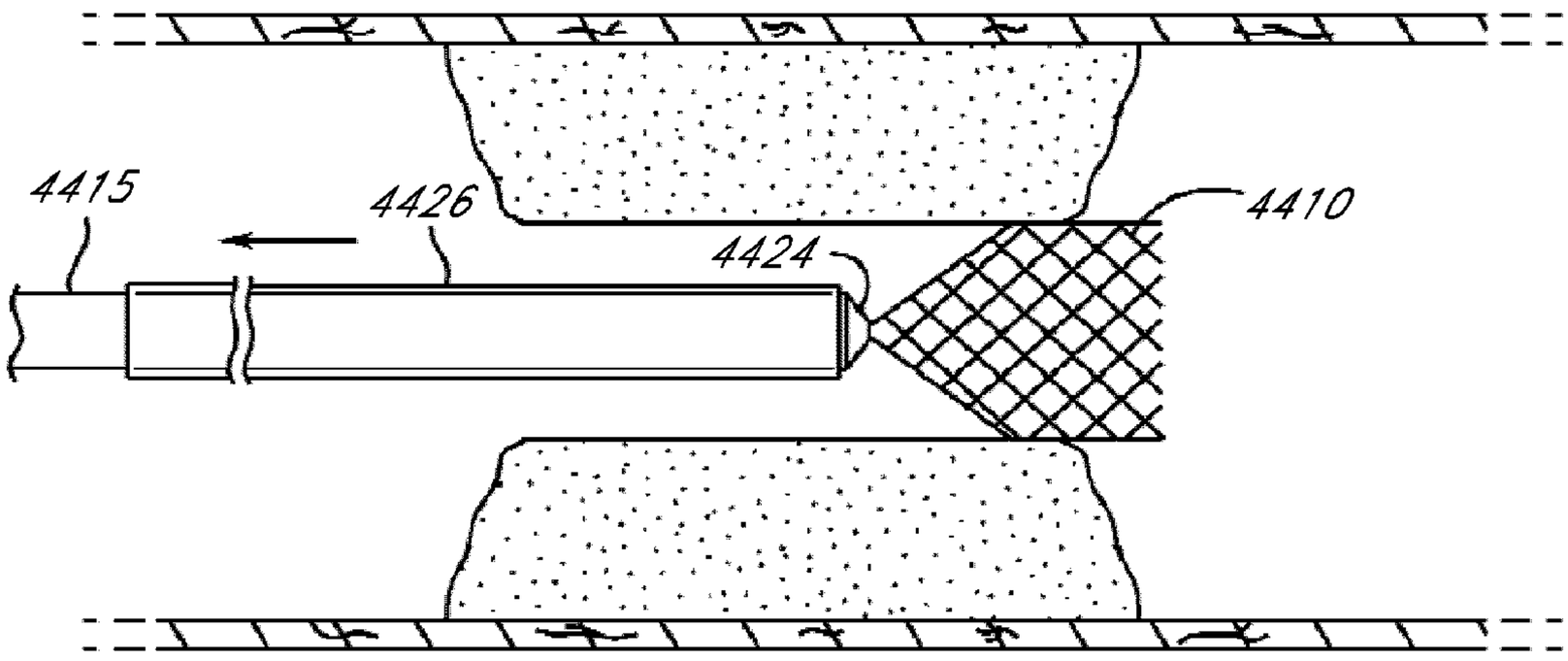

FIG. 52

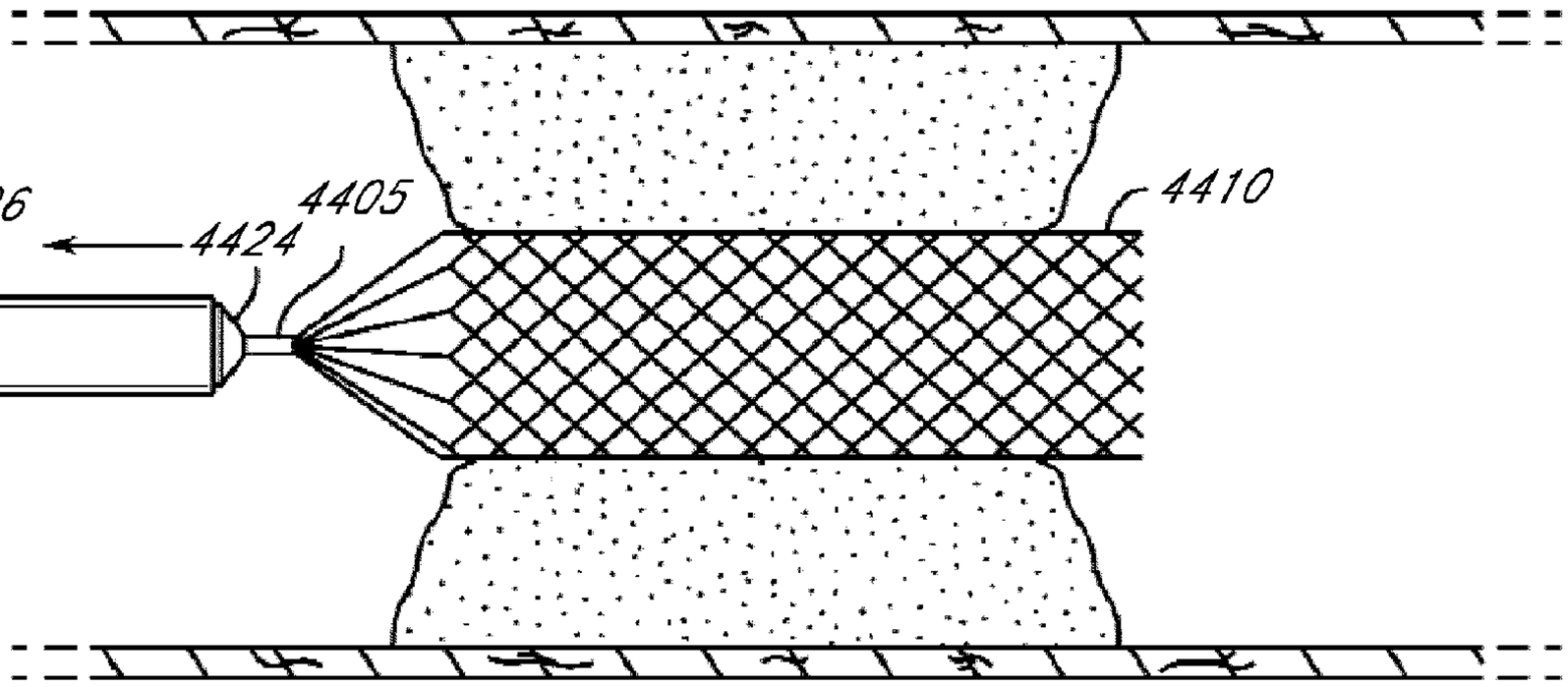

FIG. 53

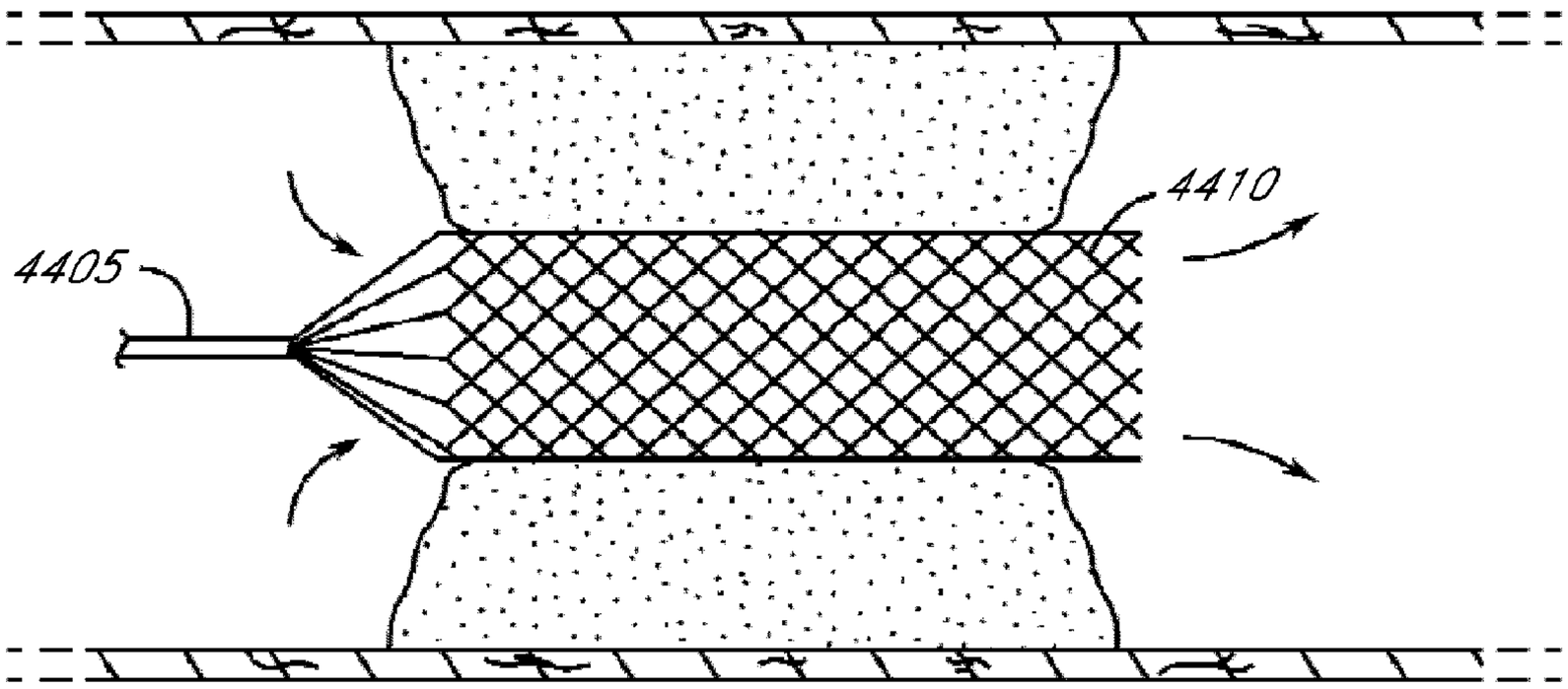

FIG. 54

BLOOD FLOW RESTORATIVE AND EMBOLUS REMOVAL METHODS

RELATED APPLICATIONS

This application claims the benefit of and priority to U.S. Provisional Application Ser. No. 61/057,613 filed May 30, 2008 and U.S. Provisional Application Ser. No. 61/166,725, filed Apr. 4, 2009 and is a continuation-in-part of each of U.S. Utility application Ser. No. 12/182,370, filed on Jul. 30, 2008; U.S. Utility application Ser. No. 12/123,390, filed on May 19, 2008; and U.S. Utility application Ser. No. 12/422,105, filed on Apr. 10, 2009; the contents of which are incorporated by reference herein in their entirety.

BACKGROUND

The present disclosure relates to stroke treatment systems. Particularly, the present disclosure relates to improved devices for restoring blood flow and embolus removal during acute ischemic stroke.

SUMMARY

According to embodiments, a process for restoring blood flow and embolus removal during acute ischemic stroke, comprises, in combination: accessing an artery having embolic/occlusion issues with a reperfusion/clot removal device, reperfusing the subject vessel with the reperfusion/clot removal device, by engaging the subject embolus, removing the subject embolus from the vessel, and withdrawing the reperfusion/clot removal device and attached embolus.

Briefly stated, improved processes and devices restore blood flow to permit autolysis of clots, or enable capture of emboli in their entirety without fragmenting while arterial access is maintained, preserving the integrity of patients' vasculature.

Disclosed is a process for restoring blood flow and embolus removal during acute ischemic stroke, comprising in combination: accessing an artery with a catheter system; locating an embolic/occluded zone within a target vessel or branch; contacting the subject embolus/clot with a reperfusion/clot removal device; reperfusing the target vessel or branch by engaging the subject embolus/clot and through autolysis; and removing the subject embolus/clot by withdrawing the reperfusion/clot removal device without fragmenting the same. The contacting step may further comprise deploying the reperfusion/clot removal device whereby a first end of the device operatively abuts the subject embolus/clot. The reperfusing step may further comprise at least one of revascularizing and recanalizing the embolic/occluded zone by manipulating the device and establishing a flow path or microcatheter access. The removing step may further comprise recapturing the device or moving an entrapped/embolized embolus/clot down the intracranial tree to a more stable location.

Also disclosed is a product by the above disclosed process.

A product for the above disclosed process may include at least one device selected from the group of everted, stent-like members, basket-like clot removal devices having everted distal tips, and hybrid devices of the first two-types. The product may further comprise nitinol or at least one of open and closed cells. The product may have variable cell size at different parts of said device. The fibrous nature of clots/emboli and cell structure may facilitate clot attachment to the device.

Also disclosed is an extraction device comprising, in combination: a microcatheter and a capturing device configured to be selectively disposed within a lumen of the microcatheter, wherein the capturing device includes an opening configured to accept passage of a clot to within the capturing device and a distal end configured to contain the clot within the capturing device. The opening may include a mouth disposed on a middle section of the capturing device, an open-cell structure of a mesh netting that contributes to the structure of the capturing device, or an everted section on a proximal end of the capturing device.

DRAWINGS

The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

FIG. **1** shows a schematic of an exemplary iteration of a device according to the present disclosure in a position near an embolus;

FIG. **2** shows a schematic of an exemplary iteration of a device according to the present disclosure in a position near an embolus with a guidewire deployed;

FIG. **3** shows a schematic of an exemplary iteration of a device according to the present disclosure in a position bridging an embolus;

FIG. **4** shows a schematic of an exemplary iteration of a device according to the present disclosure with a capturing device being deployed;

FIG. **5** shows a schematic of an exemplary iteration of a device according to the present disclosure with a capturing device bridging an embolus;

FIG. **6** shows a schematic of an exemplary iteration of a device according to the present disclosure with an embolus within a capturing device;

FIG. **7** shows a schematic of an exemplary iteration of a device according to the present disclosure in a first position;

FIG. **8** shows a schematic of an exemplary iteration of a device according to the present disclosure in a second position;

FIG. **9** likewise schematically depicts an exemplary iteration of a device according to the present disclosure in a third position;

FIG. **10** illustrates an embodiment of a device according to the present disclosure;

FIG. **11** is a perspective view of an embodiment of an acute stroke recanalization system according to embodiments of the present disclosure in a first configuration;

FIG. **12** is a perspective view of an embodiment of an acute stroke recanalization system according to embodiments of the present disclosure tailored for use with the neurovasculature in a second configuration, further illustrating modular aspects of the system as used with tethered or reconstrainable self-expanding neurological medical devices;

FIG. **12**A illustrates a detailed view of the inner catheter of FIG. **12**;

FIGS. **13**A-**13**D illustrate an embodiment of an inner catheter of the acute stroke recanalization system of FIGS. **11** and **12**;

FIGS. **14**A-**14**C illustrate a perspective view, a side view, and a front view, respectively, of an embodiment of a self-expanding revascularization device;

FIGS. **15**A-**15**D illustrate an embodiment of a revascularization device configured for eccentric coupling to a pusher;

FIGS. **16**A-**16**F, **17**A-**17**C, **18**A-**18**D, **19**A-**19**D, **20**A-**20**C, **21**A-**21**C, **22**, **23**, and **24**A-**24**F illustrate various embodiments of revascularization devices;

FIGS. **25**A and **25**B are perspective views of an embodiment of a rapid reperfusion device of the present disclosure;

FIGS. **26**A and **26**B are perspective views of an embodiment of a method for use of a rapid reperfusion device of the present disclosure;

FIG. **27**A is a side view of an embodiment of a rapid reperfusion device comprising an infusable microwire with an integrated filter;

FIG. **27**B is a side view of an embodiment of a rapid reperfusion device comprising an infusable coil;

FIG. **28**A is a side view of an embodiment of a rapid reperfusion device comprising an infusable temporary stent;

FIG. **28**B is a side view of an embodiment of a rapid reperfusion device comprising an inflatable balloon;

FIGS. **29**A and **29**B are perspective views of an embodiment of a rapid perfusion device wherein the active segment comprises a radially expandable wire;

FIGS. **30**A-**30**D are perspective views of an embodiment of a rapid perfusion device wherein the active segment comprises a covered or uncovered mesh connected to the microcatheter via tethers;

FIG. **30**E is a side view of an embodiment of an active segment comprising an open braid or covered braid configured to be connected to the microcatheter via tethers or an open braid on both the proximal and distal ends;

FIGS. **31**A-**31**D are perspective views of an embodiment of a rapid perfusion device wherein the active segment comprises a radially expanding wire mesh;

FIGS. **32-36** illustrate embodiments of a delivery system and exemplary iteration of a temporary tethered stent mechanism;

FIG. **37**A shows a side view schematic of a microcatheter with wire passing an embolus;

FIG. **37**B shows a cross-sectional schematic of an embodiment of a microcatheter wire passing by an embolus at a point of least resistance;

FIG. **38** is a side view of an embodiment of a device for capturing emboli according to the present disclosure comprising a basket for capturing the embolus;

FIG. **39** is a side view of an embodiment of a device for capturing emboli according to the present disclosure used as a safety device in a reperfusion operation;

FIG. **40** is a flow diagram of an embodiment of a method wherein an embolus is removed from a patient after a reperfusion operation is unsuccessful;

FIGS. **41** and **42** illustrate embodiments of delivery device assemblies;

FIG. **43**A shows a schematic of an exemplary iteration of a device according to the present disclosure in a first position;

FIG. **43**B shows a schematic of an exemplary iteration of a device according to the present disclosure in a second position;

FIG. **43**C likewise schematically depicts an exemplary iteration of a device according to the present disclosure in a third position; and

FIGS. **44-54** illustrate embodiments of a balloon catheter and delivery system.

DETAILED DESCRIPTION

The present inventors have discovered that many of the positives of stenting can be combined with healed revascularization/reperfusion using devices effective to impact and remove embolus. This trend now applies in the brain, and promises dramatic improvements in therapies and treatments.

The pathological course of a blood vessel that is blocked is a gradual progression from reversible ischemia to irreversible infarction (cell death). A stroke is often referred to as a "brain attack" and occurs when a blood vessel in the brain becomes blocked or ruptures. An ischemic stroke occurs when a blood vessel in the brain becomes blocked. Ischemic strokes comprise about 78% of all strokes. A hemorrhagic stroke, which account for the remaining 22% of strokes, occurs when a blood vessel in the brain ruptures. Stroke is the third leading cause of death in the United States, behind heart disease and cancer and is the leading cause of severe, long-term disability. Each year roughly 700,000 Americans experience a new or recurrent stroke. Stroke is the number one cause of inpatient Medicare reimbursement for long-term adult care. Total stroke costs now exceed $45 billion per year in US healthcare dollars.

Viable tissue that surrounds a central core of infarction has consistently been demonstrated in animal models to be salvageable if blood flow can be restored within a time window of several hours. Data from human studies with surrogate measurements of cell viability tended to support this hypothesis. Thus, current treatment strategy for ischemic stroke is based on an urgent restoration of blood flow to the ischemic tissue within the tolerance time window to prevent the permanent loss of brain cells, leading to improved outcome for the patient.

Currently there are only two FDA-approved treatment options for an acute ischemic stroke. One option is an FDA-approved intravenous (IV) delivery of Tissue Plasminogen Activator (t-PA) (Activase), which is a thrombolytic agent. The agent is designed to dissolve the blood clot that is blocking blood flow to the brain. IV t-PA is currently limited in use since it must be used within a 3 hour window from the onset of the stroke and it appears to carry an increased risk of bleeding. The second option is a thromboembolectomy device. In August of 2004, Concentric Medical received FDA approval for its MERCI™ clot removal device. Concentric achieved an approximately 50% success rate in removing clot in its trial. The Merci device is designed to capture an embolus or clot and remove it from the blocked vessel thereby restoring blood flow. The Merci device design is a corkscrewed guidewire. This device is only able to capture and remove matter that is firm or held together by itself. In most cases Merci is used in combination with drug therapy to restore blood flow. A typical procedure using Merci will take 2-3 hours to restore blood flow if at all and may take multiple passes through the vessel to either capture, macerate or open the vessel. In some cases, the Merci device may capture an embolus but then lose grasp of it and deposit it incidentally in another area of the neuro-vasculature creating a new stroke in a new territory. In some cases complications such as vessel dissection, perforation and hemorrhage arise as a result of manipulation in the vessel.

According to the instant disclosure, if autolysis is not occurring then capture of the embolus/blood clot in its entirety without fragmenting the embolus and removal of the embolus/blood clot from the body without creating a new stroke in a new territory is performed.

According to the instant disclosure, the system will allow maintained arterial access to the treatment site and provide greater support to the arterial tree by being either over-the-wire (OTW) or rapid exchange (RX). This feature will enable the embolus/blood clot to be securely captured and removed by providing support within the vessel. The OTW or RX support provided will prevent the proximal vessel from buckling or kinking during tensioning upon embolus removal. Buckling or kinking of the vessel causes the proximal vessel orifice to ovalize, thereby stripping the embolus from the capture device.

In sum, the present inventors have discovered that emboli can be removed while reperfusion is taking place using a variety of devices in the neural space.

Using everted basket-like members and everted stent-like members, emboli can be removed without compromising access, as they become enmeshed with the devices and can be removed without vessel damage.

Those skilled in the art readily understand how the procedure disclosed herein applies to other neuro-vessels. Expressly incorporated by reference, as if fully set forth herein are co-pending and prior pending U.S. Ser. Nos. 12/123,390; 60/980,736; 60/987,384; 60/989,422; 61/015,154; 61/044,392 each of which is assigned to Mindframe, Inc. (Lake Forest, Calif.) and U.S. Pat. Nos. 6,306,141; 6,485,500; 5,792,157; 5,972,019; 7,309,351; 7,201,770; 7,179,273; 7,175,607; 7,172,575; 7,160,317; 7,147,655; and 7,004,954.

It shall be understood that the present disclosure may be applied to any object within a blood vessel, including, inter alia, an embolus, a thrombus, a blood clot, a calcified legion, or any other obstruction within a vessel. Reference to any one of these is not limiting in that the device and method may be applied to any of these objects, as well as others.

Referring now to FIGS. **1-6**, there is shown a progression of steps whereby an occluded vessel, for example at the MCA/ACA bifurcation, is accessed with a microcatheter **101**. According to embodiments, a clot **50** is accessed by a microcatheter **101**, as shown in FIG. **1**.

According to embodiments, a guidewire **99** is deployed from microcatheter **101**. The guidewire may be deployed so as to cross the clot **50**, as shown in FIG. **2**. Where clot **50** may occupy a substantial portion of the vessel, the guidewire **99** may pass around or through the clot **50**.

According to embodiments, microcatheter **101** is deployed to cross at least a portion of a clot **50**. Microcatheter **101** may be guided by guidewire **99**, as shown in FIG. **3**, or may cross at least a portion of clot **50** without the aid of guidewire **99**.

According to embodiments, a capturing device **103** is deployed from a lumen of a microcatheter **101**. First, a portion of capturing device **103** may be deployed as microcatheter **101** is retracted, as shown in FIG. **4**. As the capturing device **103** is deployed, reperfusion of the vessel in the vicinity of the clot **50** may be restored at least somewhat.

According to embodiments, as a capturing device **103** is deployed from a microcatheter **101**, the capturing device **103** may expand against a clot **50**, as shown in FIG. **5**. The amount of expansion may depend on the amount of capturing device **103** that is deployed from the microcatheter **101**. Expansion may also hold the clot **50** against a wall of the vessel, such that it is not displaced while the procedure is being performed. Capturing device **103** may be manipulated and oriented to align such that acceptance of the clot **50** within capturing device **103** is facilitated.

According to embodiments, the expansion of a capturing device **103** causes a clot **50** to be within the boundaries of the capturing device **103**, as shown in FIG. **6**. The clot **50** may enter the capturing device **103** through a mouth **105**, through the natural open-cell structure of a mesh netting that contributes to the structure of capturing device **103**, or through an everted section on either one of the proximal end or the distal end of the capturing device **103**.

According to embodiments, at least the capturing device **103** is retracted to remove a clot **50** captured within the capturing device **103** from the vessel. For example, the clot **50** may be slowly pulled back until it can be drawn into the carotid siphon, then removed into the cavernous carotid, then the common carotid, and eventually removed from the body. Capturing device **103** may be manipulated to maintain the clot **50** within the capturing device **103**. For example, capturing device **103** may be rotated, retracted, or constrained such that clot **50** does not exit from capturing device **103**, such as through a mouth **105** or other openings of capturing device **103** until desired.

According to embodiments, an extraction device **1** is disclosed, comprising a microcatheter **101** and a capturing device **103**, which may be disposed within a lumen of the microcatheter **101**. Capturing device **103** may include at least one device selected from the group of everted, stent-like members, basket-like clot removal devices having everted distal tips, and hybrid devices of the first two types.

Referring to FIGS. **7-8**, according to embodiments of the present disclosure, guidewire **99** accesses and crosses a target lesion, providing a pathway for microcatheter **101**. Capturing device **103** is shown in a state of transition from a first (collapsed) position to a second (expanded) position emerging from a lumen of microcatheter **101**. According to embodiments, guidewire **99** may be at least partially disposed within a lumen of microcatheter **101**. According to embodiments of the present disclosure, capturing device **103** may include radiographic marking elements for visualization during placement.

Referring also to FIG. **9**, according to embodiments of the present disclosure, capturing device **103** is shown in a fully expanded position, whereby it functions consistently and safely such that arterial support is maintained in virtue of guidewire **99** keeping the arterial tree from mechanical stress, while embolus removal, clot capture and other procedures are done. Thus, reperfusion is established and therapy administered without risks to patients present with other devices. According to embodiments, capturing device **103** is self-expandable, such that it may expand substantially radially when removed from within the catheter. According to embodiments, additional therapies may be provided while capturing device **103** is fully expanded, for example, through another lumen of microcatheter **101**.

According to embodiments, capturing device **103** may include a portion to allow passage of a clot **50** from the exterior of the capturing device **103** to the interior of the capturing device **103**. A clot **50** may be accepted into capturing device **103** by a mouth **105**, the natural open-cell structure of a regularly woven mesh capturing device **103**, or an everted section on either one of the proximal end or the distal end of the capturing device **103**. A portion to accept a clot **50** may be disposed at a distal or proximal end the capturing device **103** or along the length of capturing device **103**.

According to embodiments, capturing device **103** may include a distal portion that is resistant to the passage of a clot **50** from the interior of the capturing device **103** to the exterior of the capturing device **103**. A closed distal end may prohibit the escape of a clot **50** out of the distal end while the capturing device **103** is retracted. For example, as shown in FIGS. **7-9**, the distal end of the capturing device **103** may be closed, such that the open-cell structure at the distal end is more confined than the open-cell structure at the middle section of capturing device **103**, mouth **105**, or other section to accept a clot **50**. Other geometries and structures are contemplated, including nets, filters, and membranes. According to embodiments, the distal end of capturing device **103** facilitates perfusion of the vessel.

As excerpted from U.S. Provisional No. 61/057,613, which is incorporated herein by reference, FIG. **10** illustrates an embolus **50** caught on an external distal tip of an embodiment of an extraction device **11** comprising a microcatheter **101** and a reperfusion/clot removal device **203**. The reperfusion/clot removal device **203** has an open "mouth" **205**. The mouth

205 spans from a proximal tip of the reperfusion/clot removal device 203 to approximately a mid-section of the reperfusion/clot removal device 203. The clot, or embolus, 50 appears to be partially caught in the mouth 205 of the reperfusion/clot removal device 203 but partially on the external surface of the distal basket region of the reperfusion/clot removal device 203. In some embodiments, the clot 50 decreases in size (e.g., a diameter and/or length of the clot 50) from use of the reperfusion/clot removal device. In one embodiment, the size of the clot, or embolus, 50 is decreased from 4-5 mm in diameter and 15 mm in length to 4 mm in diameter and 10 mm in length.

In one embodiment, an occluded artery, for example, at the MCA/ACA bifurcation is accessed with a microcatheter, then a clot is accessed using the subject reperfusion/clot removal device, allowing for reperfusion by the reperfusion/clot removal device.

In one embodiment, the reperfusion/clot removal device engages the clot by impacting the same. The nature of the open-cell structure of the device grabs the clot, which is then slowly pulled back until it can be drawn into the carotid siphon and then removed into the cavernous carotid, then the common carotid and eventually removed from the body.

Example 1

Clotting Characteristics of Swine Blood for Testing Purposes

A study was performed to evaluate swine blood for clotting characteristics under certain handling conditions. The materials used in the test included: (1) 1 liter of pig blood (no anti-coagulant), (2) Pyrex® glassware, (3) Clorox® bleach, (4) syringes, and (5) saline consisting of a multi-purpose no rub isotonic solution, (In accordance with one embodiment, the testing procedure was performed as follows: (1) pour pig blood into glassware, (2) allow pig blood to sit for 90 minutes, (3) wash the pig blood with saline, (4) allow to sit for 60 minutes, (5) remove "white" clot with cutting tools, (6) wash thoroughly with saline, and (7) measure clot dimensions. The dimensions of the clot removed from the pig blood had a length of 50 mm and a diameter ranging from 7 to 10 mm. Other disclosure can be found in U.S. Provisional No. 61/057,613, which is expressly incorporated herein by reference.

According to embodiments, a kit of parts is disclosed, comprising an extraction device 1, as described herein, and directions for use. According to embodiments, the kit of parts and/or its components may be included as part of a surgical tray.

As excerpted from U.S. Provisional No. 60/980,736, filed Oct. 17, 2007 and from U.S. application Ser. No. 12/123,390, filed May 19, 2008, which are incorporated herein by reference, FIGS. 11, 12, 12A, 13A-13D, 14A-14C, 15A-15D, 16A-16F, 17A-17C, 18A-18D, 19A-19D, 20A-20C, 21A-21C, 22, 23, and 24A-24F illustrate embodiments of revascularization devices.

According to embodiments, by leveraging a conventional self-expanding revascularization device delivery platform, a poly-modic system can be iterated which impacts, addresses and/or crosses an embolus, radially filters, and either removes the offending embolus or is optionally emplaced to address the same. A paucity of extant systems effective for such combination therapies is noted among the art.

Using endovascular techniques self-expandable tethered or reconstrainable self-expanding neurological medical devices offer instant revascularization/recanalization of MCAs and related vessels, without any of the traditional concerns associated with stenting, according to embodiments.

The catheter-based revascularization system disclosed herein allows for natural lysis, revascularization of the challenged vessels, and importantly radially filters any particulates generated, to obviate the need to be concerned with distal migration of the same, unlike prior systems or applications which include largely "off-label" usages of devices approved only for aneurysms in the brain.

The present disclosure relates to revascularization devices (e.g., reperfusion devices) used to treat, among other things, ischemic stroke. Naturally, therefore, the revascularization devices of the present disclosure are designed to be used in neuro-type applications, wherein the specifications of the present catheters and revascularization devices may be deployed in the blood vessels of the cerebral vascular system. Similarly contemplated for the revascularization systems and catheters of the present disclosure is deployment in other parts of the body wherein the specifications of the present disclosure may be used in other vessels of the body in a non-invasive manner.

According to embodiments, disclosed herein is a catheter-based revascularization system. The revascularization devices of the present disclosure are for revascularization of blood vessels. When the catheter-based revascularization system of the present disclosure is deployed into a blood vessel having an embolus, the revascularization device is expanded thereby opening the vessel so that the vessel can resume proper blood flow.

According to the instant teachings, deployment of the system of the present disclosure, establishes immediate 50% of the diameter of the lumen patency of the vessel being addressed. Among the prior art, no system having adequately small profile with flexibility to promote improved access for in-site treatment is known which may be used as a temporary (not implanted) solution. Those skilled in the art readily understand that detachment methods comprising mechanical, electrical, hydraulic, chemical, or thermal, and others are within the scope of the instant teachings.

Moreover, as the embolus dissolves, either via blood flow or by infusing lytic agents than the guidewire lumen, the deployed revascularization device radially filters larger embolus particles from traveling downstream, thereby reducing the chances of further complications. Once the blood vessel is revascularized, the revascularization device is modified to be in a removable state together with filtered detritus, and the catheter-revascularization system is removed from the blood vessels of the patient.

Likewise, in the event that no resolution of the embolus is noted in the instant revascularization system the inventors contemplate detachment and employment as a stent of the cage-like membrane. Angiographic recanalization has been associated with improvement in clinical outcome in the setting of acute stroke resulting from acute intracranial thrombotic occlusion. Anatomic limitations (tortuous anatomy, length of the occlusion, or location of occlusion) or supply limitations are among the reasons precluding use of prior art systems until the advent of the instant teachings.

Stenting has been used successfully to restore flow after abrupt reocclusion occurring after recanalization with other modalities in previous cases. Stenting has also been reported in cases in which other modalities have failed to recanalize vessels. Even if an underlying stenosis is rarely the cause of stroke, stenting may play a role by morselizing the embolic clot or trapping it against the arterial wall. In several embodiments, an acute stroke revascularization process comprises

providing a reconstrainable self-expanding microstent system, deploying a self-expanding microstent within a neurological vessel; achieving at least one of revascularization and recanalization of a subject vessel; and removing the self-expanding microstent. In some embodiments, at least one supplemental therapy is also provided, and comprises one or more of the following: pharmacological thrombolytic agents, intraarterial thrombolytics, and mechanical manipulation.

The use of intracranial stents as a method for arterial recanalization during cerebral ischemia caused by focal occlusion of an intracranial vessel has been demonstrated to have benefits in some cases. Despite the use of available pharmacological and mechanical therapies, angiographic recanalization of occluded vessels has not been adequately achieved before stent placement, in most cases.

When SAH and intracranial hematoma occurred in patients in whom balloon-mounted stents were used, they most likely resulted from distal wire perforation. The distal wire purchase needed to navigate a coronary stent into the intracranial circulation may explain the occurrence of these adverse events. Alternatively, multiple manipulations of the Merci® brand of retriever device or expansion of balloon-mounted stents may have induced microdissections in the vessel. Stents designed for intracranial navigation have better navigability and pliability. The Wingspan® brand of stent (Boston Scientific) was designed to have more radial force than the Neuroform® brand of stent and may further improve this technique. However, the act clearly needs to advance further in this area.

IA therapy for stroke has evolved during the past decade. Approval of the Merci® brand of retriever device represents a significant step toward achieving better outcomes in acute stroke for patients not suitable for IV t-PA. However, recanalization is not always achieved using this device. Therefore, additional treatment options are required, as offered for consideration herein.

Spontaneous dissection of the internal carotid artery (ICA) is one of the main causes of ischemic stroke in young and middle-aged patients, representing 10% to 25% of such cases. Because infarct due to dissection is mainly thromboembolic, anticoagulation has been recommended to prevent new stroke in patients with acute dissection, provided they have no contraindications. In the acute phase, intravenous recombinant tissue-type plasminogen activator (IV rtPA) given within 3 hours after onset of stroke due to dissection is reportedly safe and effective. However, this often needs supplemental therapy to be effective.

Endovascular treatment with stent deployment for ICA dissection with high-grade stenosis or occlusion may be most appropriate when anticoagulation fails to prevent a new ischemic event. In such cases, the MCA may be patent. However, to compare outcomes of patients with acute stroke consecutive to MCA occlusion due to ICA dissection treated either by stent-assisted endovascular thrombolysis/thrombectomy or by IV rtPA thrombolysis. Stent assisted endovascular thrombolysis/thrombectomy compared favorably with IV rtPA thrombolysis, underscoring the need for the instant device.

The main limitation of this procedure is the immediate need for an experienced endovascular therapist. The number of cases of MCA occlusion due to carotid artery dissection was quite small and represented <10% of patients admitted for carotid dissection. However, despite these promising preliminary results, potential drawbacks related to the procedure must be considered. Acute complications such as transient ischemic attack, ischemic stroke, femoral or carotid dissection, and death have been reported. Other potential hazards of endovascular treatment of carotid dissection could have been observed. On balance, the risk-benefit favors solutions like those disclosed herein.

Most patients with acute cerebrovascular syndrome with MCA occlusion consecutive to ICA dissection have poor outcomes when treated with conventional IV rtPA thrombolysis, whereas most patients treated with stent-assisted endovascular thrombolysis/thrombectomy show dramatic improvements. Further large randomized studies are required to confirm these data, which trends likewise are technical bases for the instant systems.

According to embodiments and as illustrated in FIG. **11**, catheter-based revascularization system **1000** provides a platform for lysing emboli in occluded blood vessels. Accordingly, catheter-based revascularization system **1000** generally comprises control end **1002** and deployment end **1004**. According to embodiments, control end **1002** is a portion of the device that allows a user, such as a surgeon, to control deployment of the device through the blood vessels of a patient. Included as part of control end **1002** is delivery handle **1006** and winged apparatus **1008**, in some embodiments. Those skilled in the art readily understand module **1013** (see FIG. **12**) is detachable.

According to some examples of the instant system during shipping of catheter-revascularization system **1000**, shipping lock (not shown) is installed between delivery handle **1006** and winged apparatus **1008** to prevent deployment and premature extension of revascularization device **1024** (see FIG. **12**) while not in use. Furthermore, by preventing delivery handle **1006** from being advanced towards winged apparatus **1008**, coatings applied to revascularization device **1024** are stored in a configuration whereby they will not rub off or be otherwise damaged while catheter-based revascularization system **1000** is not in use.

According to embodiments, agent delivery device **1030** provides a conduit in fluid communication with the lumen of the catheter-based revascularization system **1000** enabling users of the system to deliver agents through catheter-revascularization system **1000** directly to the location of the embolus. The instant revascularization system delivery device may be made from materials known to artisans, including stainless steel hypotube, stainless steel coil, polymer jackets, and/or radiopaque jackets. In one embodiment, the revascularization systems comprise a plurality of apertures **1018** allowing infusable lytic agents to exit radially and distally into at least a subject embolus when transmitted through agent delivery device which is in fluid communication therewith. The revascularization systems according to several embodiments herein can comprise radiopacity for imaging purposes.

Accordingly, luer connector **1032** or a functional equivalent provides sterile access to the lumen of catheter-based revascularization system **1000** to effect delivery of a chosen agent. Artisans will understand that revascularization devices disclosed herein include embodiments made essentially of nitinol or spring tempered stainless steel. Revascularization devices likewise may be coated or covered with therapeutic substances in pharmacologically effective amounts or lubricious materials. According to embodiments, coatings include nimodipine, vasodialators, sirolamus, and paclitaxel. Additionally, at least heparin and other coating materials of pharmaceutical nature may be used.

Deployment end **1004** of catheter-based revascularization system **1000** comprises proximal segment **1010** and distal segment **1020**. Proximal segment **1010**, according to embodiments, houses distal segment **1020** and comprises outer catheter **1012** that is of a suitable length and diameter for deployment into the blood vessel of the neck, head, and cerebral

vasculature. For example in some embodiments, proximal segment **1010** is from at least about 100 cm to approximately 115 cm long with an outer diameter of at least about 2.5 French to about 4 French.

Referring also to FIG. **12**, distal segment **1020** comprises inner catheter **1022** and revascularization device **1024** (as shown here in one embodiment having uniform cells, variable cells likewise being within other embodiments), which is connected to inner catheter **1022**. Inner catheter **1022**, according to embodiments, is made from stainless steel coil, stainless steel wire, or ribbon or laser cut hypotube and is of a suitable length and diameter to move through outer catheter **1012** during deployment. For example, inner catheter **1022** extends from outer catheter **1012** 38 cm, thereby giving it a total length of between at least about 143 and 175 cm (or between about 143 and 150 cm). The diameter of inner catheter **1022** according to the exemplary embodiment is 2.7 French, with an inner diameter of at least about 0.012 to 0.029 inches (or at least about 0.012 to 0.021 inches). The inner diameter of inner catheter **1022** may be any suitable diameter provided inner catheter **1022** maintains the strength and flexibility to both deploy and retract revascularization device **1024**. In one embodiment, an inner catheter **1022'** comprises a variable-pitch hypotube, as shown in FIGS. **13**A-**13**D. In some embodiments, the hypotube has an outer diameter of 0.025", 0.022", or 0.016" and an inner diameter of 0.017" or 0.008". In some embodiments, the hypotube comprises a 25TW hypotube or a 31TW hypotube. In one embodiment, the inner catheter **1022'** comprises a laser-cut, variable-pitch hypotube. Region L comprises a laser cut transition region of the variable-pitch hypotube. Regions P**1**, P**2** and P**3** comprise three regions of the variable-pitch hypotube having variable pitch. In one embodiment, the pitch decreases from region P**1** to region P**2** and from region P**2** to region P**3**.

Referring to FIGS. **11** and **12**, revascularization device **1024** is a self-expanding, reconstrictable retractable device tethered to inner catheter **1022**. Revascularization device **1024** may be made from nitinol, spring tempered stainless steel, or equivalents as known and understood by artisans, according to embodiments. Revascularization device **1024**, according to embodiments and depending on the particular problem being addressed, may be from at least about 3.5 mm to about 50 mm in its expanded state. In an expanded state, revascularization device **1024** is designed to expand in diameter to the luminal wall of blood vessel where it is deployed.

As known to artisans, revascularization device **1024** may be coated or covered with substances imparting lubricous characteristics or therapeutic substances, as desired. Naturally, the expandable mesh design of revascularization device **1024** must be a pattern whereby when revascularization device **1024** is retracted, it is able to fully retract into inner catheter **1022**. The nature of the cell type likewise changes with respect to the embodiment used, and is often determined based upon nature of the clot.

In one embodiment, a revascularization device **1024'** comprises a plurality of struts **1027** and a plurality of open cells **1029**, as shown in FIGS. **14**A-**14**C. In accordance with some embodiments, recapturability, flexibility and tracking are enabled by the struts of the revascularization device **1024'**, which permit flexion and extension to navigate through curved vessels. With reference to FIG. **4**B, one or more markers can be pressed into pre-laser cut apertures **1026** designed to matingly embrace the same.

Catheter-revascularization system **1000** is deployed through a patient's blood vessels. Once the user of catheter-revascularization system **1000** determines that the embolus to be addressed is crossed, as known and understood well by artisans, revascularization device **1024** is deployed by first positioning outer catheter **1012** in a location immediately distal to the embolus.

Then, to revascularize/reperfuse the occluded blood vessel, distal catheter **1020** is deployed in a location whereby revascularization device **1024** expands at the location of the embolus, as illustrated by FIG. **12**. The embolus is thereby compressed against the luminal wall of the blood vessel and blood flow is restored. Modular detachable segment **1013** is known also, and may be swapped out, as needed, if an Rx system is used.

As discussed above and claimed below, creating a channel for flow ideally includes making a vessel at least about half-way-patent, or 50% of diameter of a vessel being open. According to other embodiments, the channel created may be a cerebral equivalent of thrombolysis in myocardial infarction TIMI **1**, TIMI **2**, or TIMI **3**.

Restoration of blood flow may act as a natural lytic agent and many emboli may begin to dissolve. Revascularization device **1024** is designed, according to embodiments, to radially filter larger pieces of the dissolving embolus and prevent them from traveling distal to the device and potentially causing occlusion in another location. Because the revascularization device provides continuous radial pressure at the location of the obstruction, as the embolus dissolves, the blood flow continues to increase.

After the embolus is lysed, revascularization device **1024** is sheathed into outer catheter **1012** and removed from the body. According to embodiments, larger pieces of the thrombus may be retracted with revascularization device **1024** after being captured in the radial filtering process. According to embodiments, revascularization device **1024** may be detachable whereby the revascularization device **1024** may detach from catheter-based revascularization system **1000** if it is determined that revascularization device **1024** should remain in the patient. As discussed above and illustrated in FIGS. **11** and **12**, according to embodiments, catheter-based revascularization system **1000** reconstrainable attachment or attachment by tether may be optionally detachable. Revascularization device detachment methods comprise mechanical, electrical hydraulic, chemical, thermal, and those other uses known to artisans.

FIGS. **15**A-**15**D illustrate an embodiment of a revascularization device **1500** configured for eccentric coupling to a pusher. The revascularization device **1500** can be tethered to a pusher (e.g., wire or tube) by a plurality of tether lines **1502** (also shown, for example, in FIGS. **12** and **12**A). In some embodiments, the revascularization device **1500** is eccentrically coupled to the pusher (e.g., tethered off-center). In various embodiments, the revascularization device comprises an open proximal end and/or an open distal end and a generally cylindrical body (see, for example, FIGS. **12** and **12**A and **14**A-**14**C). FIGS. **16**A-**16**F, **17**A-**17**C, **18**A-**18**D, **19**A-**19**D, **20**A-**20**C, **21**A-**21**C, **22**, **23**, and **24**A-**24**F illustrate various embodiments of revascularization devices. Other disclosure can be found in U.S. Provisional No. 60/980,736 and in U.S. application Ser. No. 12/123,390, which are expressly incorporated herein by reference.

As excerpted from U.S. Provisional No. 60/987,384, filed Nov. 12, 2007 and from U.S. application Ser. No. 12/123,390, filed May 19, 2008, which are incorporated herein by reference, FIGS. **25**A, **25**B, **26**A, **26**B, **27**A, **27**B, **28**A, **28**B, **29**A, **29**B, **30**A-**30**E and **31**A-**31**D illustrate various embodiments of rapid reperfusion devices. In one embodiment, a microcatheter having an active segment reperfuses occluded blood vessels above the junction of the subclavian artery and common carotid artery. The microcatheter is used to penetrate

emboli. Once an embolus is penetrated, the active segment of the microcatheter is activated, causing it to expand radially and thereby open a channel for restored blood flow in the embolus. The blood's natural lytic action further degrades the embolus in some cases. Therapeutic agents may be administered through the microcatheter to aid in the reperfusion process. Active and passive perfusion are thus both enabled. In one embodiment, a device is disclosed comprising a distal segment having attached thereto a radially expandable active segment, a proximal segment comprising an active segment activator for radially expanding or retracting the active segment, an activation member connecting the active segment activator to the active segment. The distal segment is of a suitable diameter for use above the juncture of the subclavian artery and common carotid artery.

In one embodiment, a method is disclosed comprising providing a microcatheter having at least a distal segment, proximal segment, and active segment for use above the subclavian artery and common carotid artery, wherein the active segment is radially expandable.

In one embodiment, a catheter system for use above the juncture of the subclavian artery and common carotid artery is provided, although other uses are equally appropriate as determined by qualified medical personnel and may be introduced via a guidewire. The device operates as a standard microcatheter during introduction into a patient. The distal segment, which is remotely deployable, has attached to it an active segment that expands radially to reperfuse emboli. After reperfusion, the active segment is returned to its configuration prior to expansion and the entire microcatheter system is removed.

According to embodiments and as illustrated by an exemplary embodiment in FIG. **25**A, there is shown microcatheter **1100**. Microcatheter **1100** comprises proximal segment **1102** and distal segment **1104**. Proximal segment **1102** remains outside of the patient and is used to insert and retract microcatheter **1100**, as well as deploy active segment **1110** of distal segment **1104** during operation.

According to embodiments, catheter length and diameter are suitable for inserting into a human patient and capable of reaching a target embolus in the region above the subclavian and common carotid arteries. For example, according to embodiments, microcatheter **1100** is about 150 cm long; proximal segment **1102** is about 115 cm with an outer diameter of about 4 French and distal segment **1104** is about 35 cm with an outer diameter of about 2.7 French. In one embodiment, the microcatheter **1100** is 135 cm long, proximal segment **1102** is 90 cm long, and distal segment **1104** is 45 cm long. In one embodiment, the microcatheter **1100** has an inner diameter of 0.012". According to embodiments, a gradual decrease or stepwise in the outer diameter dimension as a function of the distal distance from proximal segment **1102**, according to embodiments. For example, proximal segment **1102** is 4 French at the most proximal end and distal segment **1104** is 2.7 French at the most distal end. Disposed between is a segment having one or more intermediate outer diameters between 4 French and 2.7 French, such as 3.4 French and 3.0 French. The inner diameter of microcatheter **1100** is 0.012 to 0.021 inches, according to embodiments, which allows microcatheter to be inserted along a preinserted guidewire or used to infuse therapeutic agents. According to embodiments, the performance of microcatheter is comparable to standard microcatheters and is designed to track over a guidewire through the neuro-vasculature.

According to embodiments, microcatheter **1100** is designed to follow a path of least resistance through a thrombus. Guidewire inserted through a thrombus tends to follow the path of least resistance through the softest parts of each thrombus. When microcatheter **1100** is inserted, it likewise follows this path of least resistance. As blood flow is restored, the natural lytic action further helps to break up the thrombus.

According to embodiments, active segment **1110** comprises a radially expandable woven mesh or coil. The mesh may be made from materials well known and understood by artisans, including polymers, fluoropolymers, nitinol, stainless steel, vectran, or kevlar. Other biocompatible materials that may be woven or coiled are similarly contemplated. Active segment **1110** is, according to embodiments, 5 mm to 50 mm in length when expanded and is designed to substantially return to its preexpansion configuration for removal of microcatheter after reperfusion. In one embodiment, active segment **1110** is 15 mm long.

As indicated above, active segment **1110** comprises a mesh. The mesh comprises a plurality of individual units, having a uniform size or spacing geometry or a variable size or spacing geometry. According to embodiments where the size or spacing geometry is variable, smaller size or spacing geometry is used to provide a tight mesh for expanding a channel through the thrombus. Larger size or spacing geometry units allow from blood flow through active segment **1110**. In one embodiment, active segment **1110** comprises a woven polymer mesh that is heparin coated. In one embodiment, active segment **1110** has a suitable porosity to permit blood flow when expanded. In one embodiment, releasing expansion of active segment **1110** will trap thrombus in the mesh.

According to embodiments, variable cell size or spacing geometry is accomplished with points where the braid crosses over fixed filaments (PICS). Thus, the cell size or spacing geometry varies by varying the density of the braid. Where high radial force is needed to open a channel in an embolus, for example, the filaments of the mesh are denser and therefore cross each other more often, yielding small cell size or spacing geometry that leads to the application of greater radial force when the mesh expands. Where perfusion is desired, the PICS are less dense and the resulting cell size or spacing geometry is increased. Additionally, drug delivery through microcatheter will be more effective in mesh configurations having a large size or spacing geometry.

Active segment **1110** may be coated or covered with substances, such as lubricious agents or pharmacologically active agents, according to embodiments. For example, active segment **1110** may be covered with heparin or other agents that are used in clot therapy, such as those that aid in dissolving clots or mitigating vasospasms.

According to similar embodiments, therapeutic agents are deployable through the lumen of microcatheter **1100**, thereby allowing users of microcatheter **1100** to determine on a case-by-case basis whether to administer an agent. Accordingly, the braid/geometry of active segment **1110** is porous to allow the agent to pass from lumen of microcatheter **1100** into the blood vessel at the site of an embolus, for example.

Activation member **1120**, according to embodiments, is a wire that connects proximal segment **1102** to distal segment **1104** and allows a user of microcatheter **1100** to deploy active segment **1110**. Accordingly, activation member **1120** is made from stainless steel wire or braid, composites polymers and metal braids, ribbon or wire coils. According to embodiments, activation member **1120** comprises a hollow lumen that slidably moves over a guidewire to insert microcatheter **1100**.

When active segment **1110** is expanded in a vessel, the radial expansion causes a channel to be formed in a thrombus for restored blood flow past the occlusion and thereby reper-

fuse the vessel. Activation of active segment **1110** is accomplished by mechanical methods, such as with activation member **1120** or by using liner of microcatheter **1110**. Use of the liner is accomplished by leaving the liner unfused with active segment **1110**.

For example, activation member **1120** fuses to the distalmost portion of activation segment **1110**. According to embodiments, activation segment **1110** is heat set into a native confirmation in an expanded state. When activation member **1120** tensions active segment **1110**, its confirmation changes from an expanded state into a deliverable state. Once delivered to the site of an embolus, activation member **1120** is adjusted to allow active segment **1110** to relax and thereby expand. According to similar embodiments, active segment **1110** is heat set into a native unexpanded confirmation. Activation member **1120** is used to tension active segment **1110** when delivered to the site of an embolus, thereby expanding it.

Other activation methods include electrical, chemical, and thermal activators, as is known and understood by artisans. Hydraulic activation may be accomplished with a balloon in the interior of the catheter that is filled with a fluid, thereby expanding the balloon, which expands active segment.

According to embodiments illustrated in FIG. **26**A, microcatheter is inserted into a vessel having an occlusion. As previously discussed, microcatheter is insertable along a guidewire through vessel lumen **1202**, according to certain embodiments. Microcatheter **1100** penetrates embolus **1210** in vessel **1200**. Active segment **1110** is positioned to coincide with the position of embolus **1210**, according to techniques well known and understood by artisans. Thereafter, active segment **1110** is expanded, thereby opening a channel in thrombus **1210** and restoring blood flow, as illustrated in FIG. **26**B.

Once activated, active segment **1110** allows blood to flow around microcatheter **1100** and active segment **1110** to create therapeutic benefits associated with reperfusion. For example and according to embodiments, the portions of distal segment **1104** immediately proximal and distal to active segment **1110** may have a diameter of 2.0 French to 3.0 French and have installed therein revascularization ports **1112**, as shown in FIGS. **26**A and **26**B. Revascularization ports **1112** comprise openings in microcatheter **1100** that allow to blood flow through microcatheter **1100**. Additionally, revascularization ports **1112** provide additional delivery points for therapeutic agents delivered through microcatheter **1100**.

According to embodiments, a filter may be placed distal of active segment to prevent embolus pieces detached in the reperfusion process from escaping and causing distal occlusions. Accordingly, active segment is designed to capture pieces of embolus during the reperfusion processes. These pieces are captured within active segment **1110** when active segment **1110** is returned to its initial confirmation after expansion.

In some embodiments, active segment **1110** comprises an infusable microwire with an integrated filter as illustrated in FIG. **27**A. In one embodiment, the infusable microwire has a diameter of 0.014". According to embodiments and as illustrated in FIG. **27**B, active segment **1110** comprises an infusable coil. In one embodiment, the infusable coil has a diameter of 0.014". Accordingly, active segment **1110** comprises a large portion of distal segment **1104**, wherein microcatheter **1100** itself coils when activated to create a channel through an embolus whereby blood flow is restored.

In some embodiments, the rapid reperfusion device comprises an infusable temporary stent as illustrated in FIG. **28**A. According to embodiments illustrated by FIG. **28**B, an infusable balloon is connected to microcatheter **1100** and comprises active segment **1110**. Inflation of the infusable balloon opens a channel through the embolus and begins the lytic process.

FIGS. **29**A-**29**D illustrate exemplary embodiments wherein active segment **1110** comprises different configurations designed to reperfuse an occluded blood vessel. According to embodiments illustrated in FIGS. **29**A and **29**B, active segment **1110** comprises an expandable coiled wire. The coiled wire may be made from stainless steel wire or braid, composite metal polymers, memory shape alloys such as nitinol, etc., wherein the coil is able to stably expand and return to its original state. As illustrated in FIG. **29**A, the diameter of coil is substantially the same as that of microcatheter **1100** when in a nonexpanded state. However, when expanded (as illustrated in FIG. **29**B) coil expands radially according to the reperfusion principles disclosed herein. According to embodiments, revascularization ports **1112** provide for increased blood flow through the lumen of microcatheter **1100**. Activation of the coil may occur as previously disclosed, for example mechanically using activation member **1120**, or by electrical or heat methods, as well known and understood by artisans.

FIGS. **30**A-**30**D illustrate an embodiment of the present disclosure wherein active segment **1110** comprises a tethered mesh. According to this embodiment, active segment **1110** comprises mesh **1110**A and tethers **1110**B. Mesh is the same as previously described. According to embodiments, mesh comprises an open braid or a covered braid. The covering comprises, according to embodiments, a distal protection mechanism and may be a polymer, such as polyurethane, or other biocompatible cover materials such as ePTFE or related thin film. Tethers **1110**B serve to provide structure for mesh **1110**A, while providing large openings whereby blood may freely flow from the proximal to distal end of active segment **1110**. Those skilled in the art will readily understand that materials for tethers and mesh may be the same, different, or interchangeable, as needed. FIG. **30**E illustrates an embodiment of an active segment comprising an open braid or covered braid configured to be connected to the microcatheter via tethers or an open braid at both the proximal and distal end, thereby forming an open proximal end and an open distal end.

As shown in FIGS. **30**A and **30**B, microcatheter **1100** is inserted along guidewire **1300**. In some embodiments, guidewire **1300** is compatible with 0.010" and 0.014". Active segment is initially in a non-expanded configuration. FIGS. **30**C and **30**D illustrate embodiments of active segment **1110** when extended. In some embodiments, active segment **1110** has an expanded diameter from 1.5 mm to 3.5 mm and therapeutic lengths of 8 mm, 12 mm, or 16 mm. In one embodiment, microcatheter **1100** has a useable length of 150 cm.

According to embodiments illustrated in FIGS. **31**A-**31**D, active segment **1110** comprises a wire mesh having variable spacing between the wires. FIGS. **31**A and **31**B illustrate active segment **1110** in a non-expanded configuration. FIGS. **31**C and **31**D illustrate active segment **1110** in an expanded position, as disclosed herein. In some embodiments, guidewire **1300** is compatible with 0.010" and 0.014". In some embodiments, active segment **1110** has an expanded diameter from 1.5 mm to 3.5 mm and therapeutic lengths of 8 mm, 12 mm, or 16 mm. In one embodiment, microcatheter **1100** has a useable length of 150 cm.

As excerpted from U.S. Provisional Application Ser. No. 60/989,422, filed Nov. 20, 2007 and from U.S. application Ser. No. 12/123,390, filed May 19, 2008, which are incorpo-

rated herein by reference, FIGS. **32-36** illustrate embodiments of a temporary tethered stent mechanism and delivery system.

In some embodiments, the devices, methods and systems described herein facilitate and enable reconstruction of a vessel wall at the neck of an aneurysm.

According to embodiments, a tethered cage-like structure functions in conjunction with a coiling microcatheter system, among other things, by stabilizing vessel walls and providing tethered cage-like therapeutic support for treating aneurysms.

According to embodiments, methods and systems function with standard microcatheters to temporarily bridge aneurysmal necks.

According to embodiments, a cage-like structure is tethered to the end of a trackable delivery distal system. By bridging the neck of an aneurysm while permitting flow, coil embolization, for example, can be performed without risking vessel embolization. The tethered cage-like structure can then be proximally withdrawn.

According to embodiments illustrated in FIGS. **32-36**, the system is optimized in a support role with other therapies.

Several methods of treating aneurysms have been attempted, with varying degrees of success. For example, open craniotomy is a procedure by which an aneurysm is located, and treated, extravascularly. This type of procedure has significant disadvantages. For example, the patient undergoing open craniotomy must undergo general anesthesia. Also, the patient undergoes a great deal of trauma in the area of the aneurysm by virtue of the fact that the surgeon must sever various tissues in order to reach the aneurysm. In treating cerebral aneurysms extravascularly, for instances, the surgeon must typically remove a portion of the patient's skull, and must also traumatize brain tissue in order to reach the aneurysm.

Other techniques used in treating aneurysms are performed endovascularly. Such techniques typically involve attempting to form a mass within the sac of the aneurysm. Typically, a microcatheter is used to access the aneurysm. The distal tip of the microcatheter is placed within the sac of the aneurysm, and the microcatheter is used to place embolic material into the sac of the aneurysm. The embolic material includes, for example, detachable coils or an embolic agent, such as a liquid polymer. The placement of these types of embolic materials suffer from disadvantages, most of which are associated with migration of the embolic material out of the aneurysm into the parent artery. This can cause permanent and irreversible occlusion of the parent artery.

For example, when detachable coils are used to occlude an aneurysm which does not have a well defined neck region, the detachable coils can migrate out of the sac of the aneurysm and into the parent artery. Further, it is, at times, difficult to gauge exactly how full the sac of the aneurysm is when detachable coils are being placed. Therefore, there is a risk of overfilling the aneurysm in which case the detachable coils also herniate or prolapse into the parent artery.

Another disadvantage of detachable coils involves coil compaction over time. After filling the aneurysm, there remains space between the coils. Continued hemodynamic forces from the circulation act to compact the coil mass resulting in a cavity in the aneurysm neck. Thus the aneurysm can recanalize.

Embolic agent migration is also a problem. For instance, where a liquid polymer is placed into the sac of the aneurysm, it can migrate out of the sac of the aneurysm due to the hemodynamics of the system. This can also lead to irreversible occlusion of the parent vessel.

Techniques have been attempted in order to deal with the disadvantages associated with embolic material migration to the parent vessel. Some such techniques, commonly referred to as flow arrest techniques, typically involve temporarily occluding the parent vessel proximal of the aneurysm, so that no blood flow occurs through the parent vessel, until a thrombotic mass has formed in the sac of the aneurysm which helps reduce the tendency of the embolic material to migrate out of the aneurysm sac. However, thrombotic mass can dissolve through normal lysis of blood. Also, in certain cases, it is highly undesirable to occlude the parent vessel even temporarily. Therefore, this technique is, at times, not available as a treatment option. In addition, even occluding the parent vessel may not prevent all embolic material migration into the parent vessel.

Another endovascular technique for treating aneurysms involves inserting a detachable balloon into the sac of the aneurysm using a microcatheter. The detachable balloon is then inflated using saline and/or contrast fluid. The balloon is then detached from the microcatheter and left within the sac of the aneurysm in an attempt to fill the sac of the aneurysm. However, detachable balloons also suffer disadvantages. For example, detachable balloons, when inflated, typically will not conform to the interior configuration of the aneurysm sac. Instead, the detachable balloon requires the aneurysm sac to conform to the exterior surface of the detachable balloon. Thus, there is an increased risk that the detachable balloon will rupture the sac of the aneurysm. Further, detachable balloons can rupture and migrate out of the aneurysm.

Cerebral aneurysms occur in approximately 2% of the population. Approximately 30,000 aneurysms are treated annually in the USA. Aneurysms grow from a weakness in a blood vessel. Origins of aneurysms are presently unknown but linked to hypertension and injury.

About 80% of aneurysms are less than 10 mm with the remainder growing to as large as 40 mm. Most large aneurysms have wide necks characterized with a neck greater than 4 mm or a dome to neck ratio less than 2:1.

In cases when aneurysms have a wide neck, either stent-assisted coiling in practice or balloon remodeling is performed to embolize the aneurysm. During stent-assisted coiling, a stent (for example, the Boston Scientific® brand of Neuroform™ system or the Johnson and Johnson Cordis® Enterprise™ brand of) structure is placed within the artery of the vessel with the aneurysm in an attempt to reconstruct the vessel wall at the neck of the aneurysm.

Patients are typically anti-coagulated and anti-aggregated with a combination of aspirin and Plavix® to mitigate the thrombo-embolic effects of a foreign body response. The patients will maintain the drug regimen long after the embolization procedure.

However, patients with sub-arachnoid hemorrhage (SAH) are not candidates for stents due the prophylactic drug regimen to mitigate the thrombo-embolic complications. A second approach is to perform balloon-remodeling. In this technique, a very soft, conformable balloon (the ev3 brand of Hyperform™ device) typically used for balloon-test-occlusion is placed in the artery at the neck to reconstruct the neck at the aneurysm origin. However, during this technique, flow arrest is performed while the balloon is inflated.

There is a risk of initiating an ischemic event during balloon remodeling and/or a thrombo-embolic event during flow arrest. This technique can be used during SAH because no additional prophylactic drug regimen is required. Once both these techniques are performed, coil embolization of the aneurysm can be performed. During the stenting procedure,

the stent is permanently implanted. During balloon remodeling, the balloon is removed once embolization is completed.

A device that can reconstruct the vessel wall at the aneurysm neck origin has been created by tethering a cage-like structure to the distal end of a trackable delivery system. For example, the MindFrame® brand of cage-like structure tethered stent can be placed across the neck of aneurysm without prophylactically administered aspirin and Plavix® as well as not obstructing flow. The tethered stent allows perfusion through the body of the structure and provides support to the neck of the aneurysm allowing coil embolization procedure the tethered stent can be withdrawn proximally into the standard delivery microcatheter.

The device is delivered through standard microcatheters currently available to the interventionalist. An embolization microcatheter can either be placed into the aneurysm prior to placement of the tethered stent or after placement of the tethered stent. If the latter is preferred then the coil embolization microcatheter must be placed through the struts of the tethered stents to access the body of the aneurysm to commence coiling. Both techniques are performed during standard stenting procedures.

Referring to FIG. **32**, delivery tube **3215** deploys tethered cage-like device/temporary stent **3210** prior to embolization, using a standard over-the-wire (OTW) system. The instant system is able to be deployed prior to embolization, used to reconstruct the arterial wall at the aneurysm neck, hold in place emboli material and then be able to be removed after embolization or the aneurysm sac is complete.

The system provides a method to assist in aneurysm embolization that does not restrict blood flow and can be used without placing patients on ASA/Plavix® during embolization. During balloon remodeling, flow arrest is performed. During stenting, patients need ASA/Plavix®.

According to the disclosure, a temporary tethered cage-like structure/tethered stent **3210** is non-detachable in some embodiments but attached either to a hypotube or guide wire **3220** allowing it to be navigated into tortuous vasculature in the brain. The device and system are deployed prior to embolization, as discussed above and claimed below. Device **3210** may be attached to guide-wire **3299** or tube **3215**.

Referring also to FIG. **33** through FIG. **35**, microcatheter/delivery tube **3215** emplaces cage-like temporary stent **3210** at aneurysm neck, while a coiling microcatheter **3203** accesses an aneurysm, and allows coil **3207** to be placed therein. Delivery tube **3215** and cage-like temporary stent **3210** are known in the art and may include Nitinol® or the like "super-elastic" materials.

FIG. **34** likewise provides further details of the instant system, with tethered cage-like structure/temporary stent **3210** being released from delivery tube **3215** using known OTW techniques.

FIGS. **35** and **36** likewise show intermediate steps, whereby placement of the system allows an aneurysm to be isolated, at the neck, whereby coils **3207** may be used. According to embodiments illustrated by FIG. **36** if coil **3207** somehow gets caught in stent **3210**, it may be impossible to remove the device without causing damage to or rupturing the vessels. Therefore, according to embodiments, stent **3210** may be detachable (e.g., via attachment mechanism **3209**), enabling it to be left in the vessel in the event a complication where it cannot be safely removed.

The delivery tube **3215** is a variable stiffness tube that is able to track to and through the tortuous anatomy or the cerebral vasculature (i.e., internal carotid artery, MCA, ACA, vertebral and basilar).

The delivery tube **3215** can be one or two pieces but must have greater proximal pushability (stiffness) & greater distal flexibility (softness) to allow tracking to distal cerebral arteries.

The delivery tube **3215** should also have a lumen that enables tracking over a guide-wire. This feature provides a few benefits: ability to track and be delivered; ability to maintain access in the event different size devices need to be exchanged; and ability to provide support to arterial tree during device deployment and recovery. A flexible device may tend to herniate or prolapse into openings. The guidewire provides a pathway (concentric) to the artery and supports the device preventing such technical complications.

The delivery tube **3215** can be mechanically attached to the tethered stent by soldering, welding or press fitting. Likewise, those skilled in the art readily understand their attachment mechanisms.

The cage-like structure/stent is made of Nitinol to allow it to be compressed and loaded into an introducer for packaging. Similarly memory-based materials likewise function, in accordance with the instant systems.

The introducer enables the device to be transferred into a microcatheter and deploy to a trusted location such as an aneurysm neck.

The cage-like structure/stent is attached to the delivery wire described previously.

By attaching it to a delivery wire, the cage-like structure/stent can be placed, retracted, repositioned and recaptured into a microcatheter.

This is an important feature. The device, being temporary, allows for the following: 1) perfusion of blood through artery during coiling; 2) perfusion from coiling herniation or prolapse; and 3) removal of the device, mitigating the use of Aspirin and Plavix.

A technical basis for the term "super-elastic" found in the class of nickel-titanium alloys known as "nitinol" alloys discovered by the United States Navy Ordinance Laboratory. These materials are discussed in length in U.S. Pat. Nos; 3,174,851 to Beuhler, et al; 3,351,463 to Rozner, et al; and 3,753,700 to Harrison, et al. Alloys known to be suitable are those containing at least 1.5% (wt) and up to about 85% (wt) or more, of one or more alloying members selected from the group consisting of vanadium, chromium, manganese, iron, and cobalt. By the term "stent" or "ribbon", we intend to include elongated shapes, the cross section of which are not square or round and may typically be rectangular, oval, or semi-oval. They should have an aspect ratio of 0.05 (thickness/width) or less, depending on application at issue. Other disclosure can be found in U.S. Provisional No. 60/989,422, which is expressly incorporated herein by reference.

As excerpted from U.S. Provisional Application Ser. No. 61/015,154, filed Dec. 19, 2007 and from U.S. Utility application Ser. No. 12/182,370, filed on Jul. 30, 2008 and U.S. Utility application Ser. No. 12/123,390, filed on May 19, 2008, which are incorporated herein by reference, FIGS. **37**A, **37**B, and **38-40** illustrate embodiments of a device and method for capturing emboli and FIGS. **41** and **42** illustrate delivery device assemblies.

In some embodiments, the devices, methods, and systems described herein facilitate and enable treatment of ischemic or hemorrhagic stroke. More specifically, a tethered basket-like system operates in conjunction with a microcatheter system, to provide arterial support and capture emboli.

In one embodiment, a device for the removal of emboli is disclosed comprising a mesh capturer having at least an undeployed state and a deployed state, the mesh capturer being inserted into the neurovasculature in an undeployed state and

removed from the microvasculature in its deployed or retracted state. wherein the mesh capturer is deployed into its deployed state distal to an embolus and advanced proximally until the embolus is substantially contained within the mesh capturer; and wherein the basket is deployed above the subclavian artery and common carotid artery. In some embodiments, the device is inserted into the vasculature over a guidewire. In some embodiments, the device is inserted into the vasculature as a component of a rapid exchange system.

In one embodiment, a method for removing an embolus is disclosed comprising inserting a microcatheter and guidewire distal to an embolus; inserting a embolus capture device over the wire through the microcatheter distal to the embolus; deploying the embolus capture device; retracting the deployed embolus capture device until the embolus is substantially contained within the embolus capture device; and removing the embolus capture device.

The ideal stent for intracranial use would be flexible, precisely delivered, retrievable, able to be repositioned, atraumatic, available in various lengths and diameters, thin-walled and radiopaque. It should provide sufficient coverage to restrain coils, while having wide enough fenestrations to permit catheterisation with coil or other embolic agent delivery catheters. The currently available over-the-wire stents are not ideal. The balloon-expandable stents of sufficient length are too stiff to be reliably and safely deployed. While existing self-expanding stents offer some improvement in this respect there are still serious difficulties in deploying them in distal locations and the currently available or planned stents for intracranial use are not available in the small diameters necessary for distal intracranial use.

The stent is delivered through a micro-catheter, allowing standard microcatheter/wire techniques to reach locations inaccessible to over-the-wire stents. A particularly appealing characteristic is its ability to be retrieved and repositioned after complete delivery, if its position is felt to be suboptimal or if the stent proves not to be necessary. The stent conforms completely to the normal vessel geometry and is not prone to strut opening on convexities. It is compatible with all currently used embolic agents for aneurysm occlusion and is MR compatible.

Stents have been used widely in occlusive lesions in the peripheral, renal, and coronary arteries to treat stenosis of vessels narrowed by a variety of pathologic conditions. Initially used mainly in extracranial cerebral vessels for carotid artery stenosis or the treatment of pseudoaneurysms of the extracranial carotid artery, small stents are now increasingly used for intracranial vessel disease such as the treatment of wide-necked aneurysms not amenable to conventional endovascular techniques.

Major limitations of the currently available stents, usually cardiac stents, however, are their relative stiffness, rendering them not flexible enough to pass the C1/C2 vertebral artery or carotid siphon tortuosities.

The design constraints for the device used in this study were to develop an endovascular stent that is flexible enough to be delivered via a microcatheter and to be placed in small vessels but with sufficient radial forces to conform to the vessel wall when deployed.

According to embodiments of the system illustrated in FIGS. **37**A, **37**B, and **38-40**, by leveraging a conventional self-expanding reperfusion device delivery platform, a polymodic system can be iterated which crosses an embolus, filters, and either removes the offending embolus or is optionally emplaced to address the same. A paucity of extant systems effective for such combination therapies is noted among the art.

According to embodiments of the system illustrated in FIGS. **37**A, **37**B and **38-40**, the system allows for natural lysis, perfusion of the challenged vessels, and importantly filters any particulates generated, to obviate the need to be concerned with distal migration of the particulates generated. In some embodiments, the emboli removal devices are used to treat, among other things, ischemic stroke. Naturally, therefore, the emboli removal devices of the present disclosure are designed to be used in neuro-type applications, wherein the specifications of the present catheters and emboli removal devices may be deployed in the blood vessels of the cerebral vascular system. Similarly contemplated for the emboli removal systems and catheters of the present disclosure is deployment in other parts of the body wherein the specifications of the present disclosure may be used in other vessels of the body in a non-invasive manner. According to embodiments illustrated in FIGS. **37**A, **37**B, and **38-40**, disclosed herein are devices and methods of the removal of neurocranial emboli without causing distal complication arising from the passing of larger pieces of a recovered embolus distal to the location of the original embolus.

According to embodiments illustrated in FIGS. **37**A, **37**B, and **38-40**, disclosed herein is a catheter-emboli removal system. The emboli removal devices of the present disclosure are for reperfusion of blood vessels. When the catheter-emboli removal system illustrated in FIGS. **37**A, **37**B, and **38-40** is deployed into a blood vessel having an embolus, the emboli removal device is expanded and moved proximally along the vessel so that the embolus is substantially contained with the mesh basket of the emboli removal device.

In one embodiment, deployment of the system illustrated in FIGS. **37**A, **37**B, and **38-40** establishes immediate 50% of the diameter of the lumen patency of the vessel being addressed by removing the embolus occluding the vessel. Among the prior art, no system having adequately small profile with flexibility to promote improved access for in-site treatment is known which may be used as a temporary (not implanted) solution and removed without substantial damage to the vasculature.

Additionally, in reperfusion applications the emboli removal device may be deployed as a safety device. As the embolus lyses, the deployed emboli removal device filters larger embolus particles from migrating distally, thereby reducing the chances of further complications. If reperfusion is unsuccessful, then the emboli removal device is retracted proximally, thereby substantially capturing the embolus. Then the entire device is removed together with the microcatheter.

According to embodiments and as illustrated in FIG. **37**A, a cross sectional view of an artery **2110** having embolus **2120** in artery lumen **2112** is shown. Guidewire **2130** inserted through a thrombus tends to follow the path of least resistance through the softest parts of embolus **2120**. When a microcatheter is inserted along guidewire **2130**, it likewise follows this path of least resistance. Accordingly, when a stent or embolus capture device is inserted via guidewire **2130**, it is deployed offset because guidewire **2130** is not centered in the vessel in many cases, as illustrated in FIG. **37**B.

To address the problem of the guidewire offset, the inventors devised an embolus capture device **2200** that is adept at capturing embolus **2120** even when deployed in an offset way. As part of the embolus capture device **2200** design, pieces of embolus **2120** that break away from embolus **2120** are recaptured to prevent potential migration more distal in the vasculature which may potentially cause other emboli, too remote to safely address.

As illustrated in FIG. **38**, blood vessel **2110** is shown having vessel lumen **2112** and embolus **2120**. As illustrated, embolus capture device **2200** is deployed for capture of embolus **2120**. As illustrated, embolus capture device **2200** is deployed along an offset guidewire. However, embolus capture device **2200** is designed for offset deployment to deploy such that it occupies about the center of vessel **2110**, which ensure maximum efficiency in the capture of embolus **2120**. It will be readily recognized that the devices of the present disclosure need not be deployed offset.

Embolus capture device **2200** comprises mesh basket **2210** and tethers **2220** which are deployed from microcatheter **2230**. Mesh basket **2210** comprises a radially expandable woven mesh or coil basket open on the proximal end and closed at the distal end. The mesh may be made from materials well known and understood by artisans, including polymers, fluoropolymers, nitinol, stainless steel, vectran, or kevlar. Other biocompatible materials that may be woven or coiled are similarly contemplated. Mesh basket **2210** connects to microcatheter **2230** via tethers **2220** and is designed to be compatible such that it is removable in its deployed state without causing dissection or other damage to the vasculature.

Mesh basket **2210** comprises a plurality of individual units, having a uniform size or spacing geometry or a variable size or spacing geometry. According to embodiments where the size or spacing geometry is variable, smaller size or spacing geometry is used to provide a tight mesh for preventing the passage of small pieces of embolus **2120** that break away. In all cases, size or spacing geometry will not allow pieces of embolus **2120** that may cause potential complications. In some embodiments, the mesh basket **2210** comprises struts having increased thickness adjacent to the proximal end **2211** of the mesh basket **2210** to provide tensile strength for opening the mesh basket **2210**, such as described in U.S. Provisional No. 61/015,154, which is incorporated by reference herein.

Tethers **2220** serve to provide structure for mesh basket **2110**, while providing large openings whereby blood may freely flow from the proximal to distal end of embolus removal device **2200**. According to embodiments, tethers **2220** are made from the same material as mesh basket **2210**. Those skilled in the art will readily understand that materials for tethers and mesh may be the same, different, or interchangeable, as needed.

During deployment of embolus capture device **2200**, mesh basket is stored in microcatheter **2230** in an undeployed state. In the undeployed state, microcatheter **2230** is advanced distal to embolus **2120** and mesh basket **2210** is deployed. According to embodiments, both mesh basket **2210** and tethers **2220** are deployed distal to embolus **2120** to prevent tethers **2220** from dislodging pieces of embolus **2120** prior to full expansion of mesh basket **2210**, thereby preventing the pieces from advancing distal to the embolus **2120** before mesh basket **2210** is in place to filter them.

After deployment, according to embodiments, embolus removal system **2200** is retracted proximally until embolus is substantially contained within mesh basket **2210**. Thereafter, mesh basket **2210** and microcatheter **2230** are removed from the vasculature of the patient. During removal of mesh basket **2210** and microcatheter **2230**, embolus **2120** is trapped within mesh basket **2210** and withdrawn from vessel **2110**. In some embodiments, a foreign body is the target of removal. The foreign body can comprise, for example, a microcoil, a medical device, a kidney stone, and/or a gallstone.

According to embodiments, microcatheter **2230** length and diameter are suitable for inserting into a human patient and capable of reaching a target embolus in the region above the subclavian and common carotid arteries. For example, according to embodiments, microcatheter **2230** is about 150 cm long; microcatheter has a proximal segment (at a control end of microcatheter **2230**) that is about 115 cm long with an outer diameter of about 3.5 French and a distal segment (at a deployment end of microcatheter **2230**) is about 35 cm with an outer diameter of about 2.7 French. The inventors contemplate, according to embodiments a gradual decrease or stepwise in the outer diameter dimension as a function of the distal distance from proximal segment, according to embodiments. For example, proximal segment is 3.5 French at the most proximal end and distal segment is 2.7 French at the most distal end. Disposed between is a segment having one or more intermediate outer diameters between 3.5 French and 2.7 French, such as 3.2 French and 3.0 French. The inner diameter of microcatheter **2230** is 0.012 to 0.029 inches, according to embodiments, which allows microcatheter to be inserted along a preinserted guidewire or used to infuse therapeutic agents. According to embodiments, the performance of microcatheter **2230** is comparable to standard microcatheters **2230** and is designed to track over a guidewire through the neurovasculature.

As illustrated by embodiments in FIG. **39**, embolus capture device **2200** may be deployed concurrently with a reperfusion device **2211**. As embolus **2120** is reperfused with reperfusion device **2211**, embolus capture device **2200** provides a safety feature whereby pieces of embolus **2120** that break away are captured in mesh basket **2210** and removed with the reperfusion device generally. Additionally, as vessel **2110** reperfuses due to natural lytic action, mesh basket **2210** provides a minimum particle size permitted to pass distal to embolus capture device **2200**. Consequently, embolus capture device **2200** prevents further complications distal to the original site of the occlusion by preventing larger embolus **2120** pieces or particles from passing deeper into the neurovasculature and occluding it in more distal locations.

Alternately and as illustrated according to embodiments in FIG. **40**, embolus capture device **2200** is used after reperfusion is unsuccessfully attempted or not successful to the desired level. Accordingly, microcatheter **2230** is inserted into the neurovasculature in operation **2502** as well known and understood by artisans. Reperfusion is attempted, for example with the reperfusion device **2211** of FIG. **39** in operation **2504** of FIG. **40**. In some embodiments, a catheter-revascularization system is deployed through a patient's blood vessels. Once the user of catheter-revascularization system determines that the embolus to be addressed is crossed, a revascularization device (e.g., reperfusion device **2211**) is deployed by first positioning an outer catheter (e.g., microcatheter **2230**) in a location immediately distal to the embolus. Then, to revascularize, or reperfuse, the occluded blood vessel, the reperfusion device is deployed in a location whereby the reperfusion device expands at the location of the embolus. The embolus is thereby compressed against the luminal wall of the blood vessel and blood flow is restored. After reperfusion is attempted, the success is determined in operation **2506**. For example, a contrast dye is used to determine the level to which the occluded vessel is reperfused, as is well known to artisans.

If reperfusion is not successful to a desired degree, then embolus capture device **2200** is inserted through the microcatheter **2230** as described herein and deployed distal to the embolus **2120**. For example, creating a channel for flow ideally includes making a vessel at least about halfway-patent, or 50% of diameter of a vessel being open. According to embodiments, the channel created may be a cerebral equiva-

lent of thrombolysis in myocardial infarction (TIMI) **0**, TIMI **1**, or TIMI **2**, TIMI **3**, and thrombolysis in cerebral infarction (TICI) and TICI **3**. In these cases, blood flow is not accomplished to a desired degree. It is therefore desirable to remove the entire embolus. Thus, after embolus capture device **2200** is deployed distal to the embolus, it is retreated proximal until embolus **2120** is substantially inside of mesh basket **2210** in operation **2512**. Thereafter, mesh basket **2210**, embolus **2120**, and microcatheter **2230** are removed.

The embolus capture devices of the present disclosure may be designed for over the wire deployment or rapid exchange deployment, according to embodiments.

In one embodiment, ischemic stroke reperfusion or clot capture is performed by a reperfusion device or embolus capture device comprising a NiTi cut tube.

One embodiment for ischemic stroke clot retrieval includes an eccentric design. This embodiment addresses the problem during clot removal of the thrombectomy device being forced off-center because of microcatheter positioning after the microcatheter/guidewire passes the embolus. This "off-centering" causes the device to miss the embolus when pulled proximal to attempt to capture it or fragmenting will occur because the device will shave the embolus. In some embodiments, an off center delivery system is used to capture the embolus. In some embodiments, the struts are designed or favored to the periphery of the artery as opposed to the center of the artery. In some embodiments, the struts are designed to accumulate in 270 degrees of the thrombectomy device allowing open space for the embolus to fall into. By making the attachment point off-center, the open area is increased. By making the device off-center from the point of attachment to the delivery system, the device must increase the chance of capturing the embolus, which is also off-center from the microcatheter.

The chart below illustrates several ischemic stroke delivery system assembly embodiment options:

1st Option		2nd Option	
Hypo: (24 TW)	.022" × .014"	Hypo:	.0215" × .0155"
Ribbon Coil:	.003" × .005" × .015"	Ribbon Coil:	.003" × .005" × .015"
PET Heat Shrink:	.027" × .00025" Wall	PET Heat Shrink:	.027" × .00025" Wall
or	.028" × .0004" Wall		
3rd Option		**4th Option**	
Hypo:	.022" × .014"	Hypo:	.0215" × .0155"
Ribbon Coil:	.003" × .010" × .015"	Ribbon Coil:	.003" × .010" × .015"
PET Heat Shrink:	.027" × .00025" Wall	PET Heat Shrink:	.027" × .0025" Wall
or	.028" × .0004" Wall		

In some embodiments, the delivery systems maintain an outer diameter at the solder joint of 0.024" max. In some embodiments, the PET heat shrink is installed over the distal 45 cm of the delivery device. In some embodiments, the distal tip of the delivery system is trimmed after installation of the PET heat shrink. In some embodiments, the distal and_proximal ends of the delivery system are deburred. In some embodiments, the delivery systems must accept a 0.010" guidewire.

FIG. **41** illustrates embodiments of a distal end of a hypotube assembly **4100** that includes a solder joint **4111** between a hypotube **4112** and a ribbon coil **4113** and a PET heat shrink **4114**. FIG. **41** illustrates example outer diameter and length dimensions of the delivery system assembly.

The chart below illustrates dimensions for embodiments of the hypotube assembly, or delivery system.

Design	Hypotube OD	Ribbon Coil	PET	PET Prox	PET @ Joint	PET Distal
1	.022" × .014" 24 TW	.003" × .005" × .015"	0.027" × .00025" × 45 cm	.023"	.024"	.023"
2	.022" × .014" 24 TW	.003" × .010" × .015"	0.027" × .0025" × 45 cm	.023"	.024"	.023"
3	.0215" × .0155"	.003" × .005" × .015"	0.027" × .0004" × 45 cm	.022"	.025"	.0225"/.023"
4	.0215" × .0155"	.003" × .010" × .015"	0.027" × .0004" × 45 cm	.022"	.025"	.0225"/.023"
5	.022" × .014"	.002" × .010" × .017"	0.028" × .0004" × 45 cm	.022"	.0245"	.023"/.025"

The embodiments disclosed in the tables above accept a 0.010 G.W. (guidewire) straight. In some embodiments, the distal tip of the hypotube **4112** is ground (e.g., to 0.0175") to accept the inner diameter (e.g., 0.015") of the ribbon coil **4113**. The distal tip of the hypotube **4112** is soldered to the proximate tip of the ribbon coil **4113**. The PET **4114** is cut to 45 cm, the heat shrink is heated to 400 degrees Fahrenheit, and restrained while heated.

Example 2

In Vitro Tracking Evaluation Test

A study was performed to evaluate in-vitro tracking of embodiments of delivery system. The testing equipment included: a FlowTek A201 with stroke model, a 5F CORDIS® ENVOY™ MPD guide catheter, a 135 cm×0.027" inner diameter CORDIS® MASS TRANSIT™ microcatheter, and a 0.010 diameter×200 cm length TRANSEND® guidewire. The study used the following numbered scoring system: (1) pass with no friction at all; (2) pass with acceptable friction; (3) pass with some friction; (4) pass with difficulty; (5) can't pass.

Design #	Curve 1	Curve 2	Curve 3	Curve 4	PCOM	A1/M1	M2/M3
1	2/3	2/3	2/3	2/3	2/3	2/3	2
2	3	3	3	3	3	3	2
3	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	2	2	2	2	2	2	2
5	1	1/2	1/2	1/2	1/2	1/2	1/2

The following notes were taken from the study regarding guidewire tracking. Design **1** passed fine until the PCOM segment with a score of 4. Design **2** experienced some friction

requiring 300 cm of exchange wire with a score of 3/4. Design **4** scored a 5 at curve **4**. Design **5** scored a 4 generally. Designs **3** and **4** had a 0.0155" inner diameter and designs **1** and **2** had a 0.014" inner diameter. Design **5** had a 0.002"×0.010"× 0.018" hypotube ribbon coil.

FIG. **42** illustrates an embodiment of a distal end of a delivery system assembly **4200**. In one embodiment, the delivery system assembly **4200** includes a proximal hypotube **4212**, a distal braid **4213** and a polyimide liner **4215**. In one embodiment, the polyimide liner **4215** may be a braid. In one embodiment, the braid needs 0.00065" wire.

Strut thicknesses for the recanalization or reperfusion devices described herein can include 0.0040", 0.0025", 0.0020", and 0.0009". The strut thicknesses may vary. The devices may be used for reperfusion and may be tethered. The devices may or may not be recapturable and may or may not include markers.

In some embodiments, the devices described herein are to be used for clot removal and comprise a clot basket or spiral basket. In one embodiment, the clot removal device comprises a woven retrieval basket. The woven retrieval basket may include features such as an over the wire design, low porosity fine wires in the basket area to support a clot (wire dia: 0.035 mm and 56-97 pics/cm), or thicker wires that open the basket and give it tensile strength (wire dia: 0.076 mm). The woven retrieval basket may also be fully automatable.

In another embodiment, a reperfusion catheter device includes a nitinol braid. In one embodiment, the braid includes 24 strands with a wire size of 0.076 mm, a braid angle of 42 degrees, an expanded diameter of 3.5 mm, and a collapsed diameter of approximately 0.030". Other disclosure can be found in U.S. Provisional No. 61/015,154, which is expressly incorporated herein by reference.

As excerpted from U.S. Provisional Application Ser. No. 61/044,392, filed Apr. 11, 2008 and from U.S. Utility application Ser. No. 12/422,105, filed Apr. 10, 2009, which are incorporated herein by reference, FIGS. **43**A-**43**C illustrate embodiments of rapid exchange neuro-microcatheter delivery systems.

In some embodiments, microcatheter devices and therapy schemes are provided whereby access is maintained during capture of emboli/thrombi/clot material without compromise to reperfusion of blood flow. The instant disclosures include microcatheters having at least second lumens for vessel stability during removal of emboli and/or in adjunct therapy modes, these devices are referred to as "Rapid Exchange" or RX systems.

Devices, processes and systems facilitate and enable treatment of acute stroke conditions, providing reperfusion while therapy is made available by preserving structure in the arterial tree. Using a Rapid Exchange approach with at least dual lumens in a microcatheter facilitates embolus/clot removal without damaging sensitive vasculature.

The rapid exchange system described with reference to FIGS. **43**A-**43**C allows and maintains arterial access to treatment sites, and provides enhanced support to the arterial tree, while working as a rapid exchange system. This enables secure capture of emboli/thrombi/clot material by providing support within the vessel. The RX support provided prevents the proximal vessel from buckling or kinking during tensioning upon embolus removal. This is a key feature, in that the literature is demonstrative of ovalizing, whereby stripping of the embolus from capture devices happens when buckling or kinking happens.

Several methods of treating stroke have been attempted, with varying degrees of success. However, according to the instant teachings, blood can be reperfused or emboli/thrombi/clot material can be removed from the neurovasculature consistently and safely with arterial support and access maintained during the procedure.

Other techniques used in addressing this issue comprise coextruded microcatheters having multi-lumen structures, as would be known to Artisans based on this disclosure.

According to the disclosure, an OTW system, using a guidewire (sizing ranges from 14 to 18, such as the TRANSEND® or SYNCRO® brands) and a microcatheter (0.010 to at least about 0.28 maximum) having a delivery system tube (such as the MASS TRANSIT® or RENEGADE® brands) approximately sized is combined with a rapid exchange system as discussed above. The OTW system may be configured to fit within a lumen of the RX system. A microcatheter may be configured to fit within another lumen of the RX system.

The rapid exchange delivery catheter functions with, for example CORDIS® brands of microcatheters available from them, and is assembled as detailed below in the claims, or as known to those skilled in the art.

Referring now to FIG. **43**A, according to embodiments of the present disclosure, guidewire **4399** accesses and crosses a target lesion, providing a pathway for RX microcatheter **4301** having at least two lumens. Stroke device **4303** is shown in a state of transition from a first (collapsed) position to a second (expanded) position emerging from a lumen of RX microcatheter **4301**. According to embodiments, guidewire **4399** may be at least partially disposed within one of the two lumens of RX microcatheter **4301**.

Referring now to FIG. **43**B, according to embodiments of the present disclosure, stroke device **4303** includes radiographic marking elements **4305** for visualization during placement. Referring now also to FIG. **43**C, stroke device **4303** is shown in a fully expanded position, whereby it functions consistently and safely such that arterial support is maintained in virtue of guidewire **4399** keeping the arterial tree from mechanical stress, while embolus removal, clot capture and other procedures are done. Thus, reperfusion is established and therapy administered without risks to patients present with other devices. According to embodiments, as shown in FIG. **43**C, stroke device **4303** may be tethered such that, while emplaced at a treatment site within a blood vessel, it remains accessible via a microcatheter and readily retrievable therein while maintaining reperfusion of the blood vessel. According to embodiments, stroke device **4303** may be emplaced on a long-term of permanent basis, or as needed based on the amount and type of recanalization prescribed. According to embodiments, stroke device **4303** is self-expandable, such that is may expand substantially radially when removed from within the catheter. According to embodiments, additional therapies may be provided while stroke device **4303** is fully expanded, for example, through another lumen of RX microcatheter **4301**.

According to embodiments of the present disclosure, a process for making a neuro-monorail microcatheter is disclosed. The process may include cutting a first microcatheter at a distal end. A segment may be cut at about 5 cm to 50 cm from a distal end of the microcatheter. The segment of the first catheter may be aligned adjacent to a distal section of a second microcatheter. Guidewires may be placed in each of first and second microcatheters to maintain their respective alignments and keep their lumens open. A resin, such as Polyethylene terephthalate (PET), may be applied in short segments along the lengths of the first and second microcatheters to secure and maintain alignment and adjacent status of the finished device.

According to embodiments of the present disclosure, a first and second catheter, as described above, may be co-extruded and skived, in lieu of the cutting discussed above, and joined as discussed above. Other disclosure can be found in U.S. Provisional No. 61/044,392, which is expressly incorporated herein by reference.

As excerpted from U.S. Provisional Application Ser. No. 61/166,725, filed Apr. 4, 2009, which is incorporated herein by reference, FIGS. **44-54** illustrate embodiments of balloon catheter and delivery systems, and methods of use thereof.

According to embodiments of the present disclosure, a device and method are disclosed for treating occlusions of blood vessels, veins, and arteries, including neurovasculature, such as above the carotid artery. Occlusions may be partial or complete, and may be attributable to one or more of emboli, thrombi, calcified lesions, atheroma, macrophages, lipoproteins, any other accumulated vascular materials, or stenosis. According to embodiments, the systems and methods of the present disclosure facilitate lysis of such occlusions.

With reference to FIGS. **44-46**, according to embodiments of the present disclosure, a balloon catheter and delivery system **4410** may include a catheter **4420** and a balloon **4426**. The system **4410** may have a distal end **4424** and a proximal end **4422** (not shown).

With reference to FIG. **47**, according to embodiments of the present disclosure, a balloon catheter and delivery system **4410** may comprise a proximal end **4422**, a distal end **4424** and at least one lumen. A catheter **4420** may be of any length for performance of minimally invasive vascular treatments. For example, for treatment of stroke, aneurysm, or other treatments within the brain of a patient, a catheter **4420** may have a length of between about 135 cm and about 150 cm.

The catheter **4410** may be of variable stiffness that is able to track to and through the tortuous anatomy or the cerebral vasculature (i.e., internal carotid artery, MCA, ACA, vertebral and basilar). The catheter **4410** may be one or two pieces and may have greater proximal pushability (stiffness) and greater distal flexibility (softness) to allow tracking to distal cerebral arteries.

According to embodiments, there may be provided at least one balloon **4426** near a distal end **4424** of a catheter **4420** for lumen dilatation, treatment of ICAD, vasospasm, flow arrest and remodeling of aneurysm necks during embolization coiling. According to embodiments, a balloon **4426** may be disposed outside the outer surface of catheter **4420**, such that the catheter is concentrically disposed within a portion of balloon **4426**, and such that balloon **4426** expands radially away from catheter **4420**. The balloon **4426** may be a percutaneous transluminal angioplasty ("PTA") balloon. Such balloons are known in the art. According to embodiments, a plurality of balloons **4426** may be provided on an outer surface of catheter **4420**. According to embodiments, a balloon **4426** may have a diameter in an inflated state of between about 0.010" and about 0.035".

A balloon **4426** may be comprised of materials such as Pebax, nylon, PTFE, polyethylene terephthalate ("PET"), polyurethane, polyester, an elastomeric material, or other suitable materials or mixtures thereof. A balloon **4426** may be of any length that facilitates adequate crossing of an occlusion. For example, a balloon **4426** may be between about 1.5 cm and about 4.0 cm in length.

According to embodiments, at least one inflation lumen **4429** may provide fluid communication to the balloon **4426** from the proximal end **4422** of the catheter **4420**. An inflation lumen **4429** may provide a fluid to the inner portion of the balloon **4426**, such that the fluid fills and inflates the balloon **4426**. The inflation lumen **4429** may be open at or near proximal end **4422** of the catheter **4420**, and may be configured to interface with a luer adaptor, fitting, handle, syringe, injector, plunger, or any other one or more selectable items for operation of the balloon catheter and delivery system by a user. Likewise, using ePTFE, FEP, PRFE, or other known and lubricious and/or drug eluting elements with the lumens **4428** and/or **4429** is contemplated.

According to embodiments, an expandable device **4430** may be configured to be disposable within the delivery lumen **4428**. The expandable device **4430** may include a tether **38** and a cage-like structure **4436**. Tether **4438** may be attached to the cage-like structure **4436** and may be selectively detachable. Tether **4438** may extend to or beyond the proximal end **4422** of catheter **4420**. The expandable device **4430** may be disposable and trackable within the delivery lumen **4428** of the catheter **4420**.

According to embodiments, at least a portion of a cage-like structure **4436** may be tapered at or near a point of attachment with a tether **4438**. For example, a design may be provided tapering from the diameter of the tether **4438** to the largest diameter of the cage-like structure **4436**. Likewise, alternate geometric configurations for this aspect of the instant teachings are contemplated to be within the scope of the present disclosure: everted, scalloped, and other variant ends, edges are prototyped and being used.

An example of an expandable device **4430** may be the IRIIS™ brand system for restoring blood flow in a thrombotic neurovascular occlusion in patients experiencing an ischemic stroke, by MindFrame®, Incorporated.

According to embodiments, a cage-like structure **4436** may be made of Nitinol to allow it to be compressed and loaded into an introducer for packaging. Similarly, "superelastic" materials and memory-based materials likewise function, in accordance with the instant systems. According to embodiments, the cage-like structure **4436** may be compressible and expandable, such that it may maintain a compressed state when within a lumen and may maintain an expanded state when outside the lumen. According to embodiments, the cage-like structure **4436** may be "self-expanding", such that it expands once unsheathed from the delivery lumen **4428** of the catheter **4420**.

According to embodiments, by attaching it to a delivery wire, the cage-like structure **4436** can be placed, retracted, repositioned and recaptured into a catheter. These features allow for the following: 1) perfusion of blood through artery during coiling; 2) perfusion from coiling herniation or prolapse; and 3) removal of the device, mitigating the use of Aspirin and Plavix.

According to embodiments, delivery lumen **4428** may have an inner diameter to accommodate the cage-like structure **4436**. According to embodiments, at least one delivery lumen **4428** may provide a pathway through the catheter **4420** from about the proximal end **4422** of the catheter **4420** to about the distal end **4424** of the catheter **4420**. A delivery lumen **4428** may be open at or near proximal end **4422** of the catheter **4420**, and may be configured to interface with a luer adaptor, fitting, handle, syringe, injector, plunger, or any other one or more selectable items for operation of the balloon catheter and delivery system by a user. As discussed, PTFE, FEP, ePTFE and other lubricious and/or eluting elements are incorporated within at least the lumen **28**.

According to embodiments, delivery lumen **4428** be lined with polytetrafluoroethylene ("PTFE") or a polymer thereof, alone or in combination with other materials, coatings, coverings, or delivery surfaces or substrates.

According to embodiments, the catheter **4420** and the expandable device **4430** may be configured to travel together, such that the expandable device **4430** may selectively accompany the catheter **4420** as the catheter **4420** travels through or is emplaced within a vasculature. For example, the catheter **4420** and the expandable device **4430** may be jointly delivered to a location while the cage-like structure **4436** remains within delivery lumen **4428**.

According to embodiments, the catheter **4420** and the expandable device **4430** may be configured to be separately disposable, such that they may be moved relative to each other. For example, the expandable device **4430** may be advanced or retracted relative to the catheter **4420** by advancement or retraction of only the tether **4438** at the proximal end **4422** of the catheter **4420**. Likewise, the catheter **4420** may be advanced or retracted relative to the expandable device **4430** by advancement or retraction of only the catheter **4420**.

According to embodiments, catheter **4420** may be configured to provide tracking over a guide-wire (not shown). One or more lumens of catheter **4420** may provide a pathway for a guide-wire using an over-the-wire (OTW) system.

According to embodiments, a method is disclosed for treatment of a vascular occlusion, particularly a neurovascular occlusion. With reference to FIG. **48**, according to embodiments of the present disclosure, a balloon catheter and delivery system **4410** may be provided to an occlusion.

With reference to FIG. **49**, according to embodiments of the present disclosure, a balloon catheter and delivery system **4410** may cross the occlusion by leading with distal end **4426** of catheter **4420**. Crossing may be effectuated by pressure, force, ablation, or application of one of various types of energy at the distal end **4426** of the catheter **4420**. Crossing may create an initial channel by displacement of the occlusion in the presence of the balloon catheter and delivery system **4410**.

With reference to FIG. **50**, according to embodiments of the present disclosure, a balloon **4426** may be inflated or a catheter **4420** may otherwise be dilated. Inflation of balloon **4426** may further displace or compress at least a portion of the occlusion away from the catheter **4420**. Thereby, a broader channel may be created by balloon **4426**, wherein the diameter or cross sectional area of the channel exceeds the diameter or cross sectional area of the catheter **4420**.

With reference to FIG. **51**, according to embodiments of the present disclosure, the balloon **4426** may be deflated, whereby the broader channel exceeding the size of the catheter **4420** remains open at least temporarily.

With reference to FIG. **52**, according to embodiments of the present disclosure, the catheter **4420** may be withdrawn from an occlusion. The operation of withdrawing the catheter **4420** may simultaneously result in unsheathing and deployment of the cage-like structure **4436**. Deployment of the cage-like structure **4436** may result in an expansion of any portion of the cage-like structure **4436** that is not within the lumen **4428** of the catheter **4420**.

With reference to FIG. **53**, according to embodiments of the present disclosure, the catheter **4420** may be withdrawn such that the cage-like structure **4436** may achieve a fully deployed state. For example, a fully deployed state may be achieved when the entire length of the cage-like structure **4436** is outside the delivery lumen **4428** of catheter **4420**, or when at least a length of the cage-like structure **4436** corresponding to the length of the occlusion is outside the delivery lumen **4428** of catheter **4420**. Expansion of the cage-like structure **4436** may maintain the approximate size and dimensions of the broader channel created by previously inflating balloon **4426**.

With reference to FIG. **54**, according to embodiments of the present disclosure, the cage-like structure **4436** may achieve a temporary or long-term steady-state fully deployed state, wherein improved flow may be achieved through the occlusion. The flow through the channel may facilitate lysis of the occlusion and its constituent parts. The cage-like structure **4436** may maintain the channel created by the dilation or inflation of the balloon **4426**, even as the channel deforms or is otherwise modified by the improved flow. According to embodiments, the cage-like structure **4436** may be maintained within the channel of the occlusion.

According to embodiments, the cage-like structure **4436** may be retracted into the delivery lumen **4428** of the catheter **4420**, and the catheter **4420** may be removed from the location of the occlusion.

While the apparatus and method have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.

Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms—even if only the function or result is the same.

Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference. In addition, as to each term used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood as incorporated for each term and all definitions, alternative terms, and synonyms such as contained in at least one of a standard technical dictionary rec-

ognized by artisans and the Random House Webster's Unabridged Dictionary, latest edition are hereby incorporated by reference.

Finally, all references listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/these invention(s), such statements are expressly not to be considered as made by the applicant(s).

In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.

Support should be understood to exist to the degree required under new matter laws—including but not limited to United States Patent Law 35 USC 132 or other such laws—to permit the addition of any of the various dependencies or other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

Further, the use of the transitional phrase "comprising" is used to maintain the "open-end" claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term "comprise" or variations such as "comprises" or "comprising", are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.

Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

The invention claimed is:

1. A method for restoring blood flow in an occluded cerebral blood vessel of a patient during acute ischemic stroke, comprising:

accessing an cerebral blood vessel having an occluded zone with a catheter system, the catheter system comprising a microcatheter and an embolus removal device;

wherein the embolus removal device comprises a self-expandable member configured to be delivered through the microcatheter in a compressed configuration and deployed to an expanded configuration upon retraction of the microcatheter,

wherein the self-expandable member comprises a generally cylindrical body having a cell structure configured to facilitate embolus attachment to the self-expandable member;

locating the occluded zone within the artery caused by an embolus;

advancing the catheter system to the location of the occluded zone;

deploying the self-expandable member to the expanded configuration at the location of the occluded zone by retracting the microcatheter such that the self-expandable member engages and captures the embolus upon deployment of the self-expandable member,

wherein the embolus is at least partially engaged and captured on an external surface of the self-expandable member; and

removing the embolus by withdrawing the embolus removal device.

2. The method of claim **1**, wherein a first end of the self-expandable member operatively abuts the embolus.

3. The method of claim **1**, wherein engaging the embolus facilitates autolysis of the embolus or any fragments of the embolus remaining in the artery.

4. The method of claim **1**, the removing step further comprising moving the engaged embolus down the intracranial tree to a more stable location.

5. The method of claim **1**, wherein the cell structure of the body of the self-expandable member comprises variable cell size at different portions of the body.

6. The method of claim **1**, wherein a distal end of the self-expandable member of the embolus removal device is open in the expanded configuration.

7. The method of claim **1**, wherein said self-expandable member is permanently coupled to a distal end of a delivery member by a plurality of tether lines.

8. The method of claim **1**, wherein the embolus resides at least partially within the capture device upon being captured.

9. The method of claim **5**, wherein the cell size of the body of the capturing device is larger in the middle section of the body.

10. A method for restoring blood flow in an occluded cerebral blood vessel of a patient, comprising:

accessing a cerebral artery having an occluded zone with a catheter system, the catheter system comprising a microcatheter and a blood flow restoration device,

wherein the blood flow restoration device comprises a distal self-expandable capture device and a proximal delivery member,

wherein the distal self-expandable capture device is eccentrically coupled to the proximal delivery member by a plurality of tether lines,

wherein the distal self-expandable capture device is configured to be delivered through the microcatheter in a compressed configuration and deployed to an expanded configuration upon retraction of the microcatheter;

locating the occluded zone within the artery caused by an occlusive object;

advancing the catheter system to the location of the occluded zone;

deploying the distal self-expandable capture device to the expanded configuration at the location of the occluded zone by retracting the microcatheter such that the capture device engages and captures the occlusive object upon deployment of the capture device,

wherein the occlusive object is at least partially engaged and captured on an external surface of the capture device; and

removing the occlusive object by withdrawing the blood flow restoration device.

11. The method of claim **10**, wherein the occluding object comprises any one of the following non-limiting examples: an embolus, a thrombus, a blood clot, a calcified lesion, or any other obstruction within a blood vessel.

12. The method of claim **10**, wherein the occlusive object resides at least partially within the capture device upon being captured.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,088,140 B2
APPLICATION NO. : 12/475389
DATED : January 3, 2012
INVENTOR(S) : Ferrera et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Title Page 2 Item [56], Column 1, Line 14, under U.S. Patent Documents, change "Schmaltz" to --Schmaltz et al.--.

On Title Page 2 Item [56], Column 2, Line 43, under U.S. Patent Documents, change "Lee et al." to --Kilpatrick et al.--.

On Title Page 4 Item [56], Column 1, Line 38, under U.S. Patent Documents, change "Miloslayski" to --Miloslavski et al.--.

On Title Page 5 Item [56], Column 1, Line 18, under Other Publications, change "Eric Sauvegeau," to --Eric Sauvageau,--.

On Title Page 5 Item [56], Column 1, Line 36, under Other Publications, change "depolyable." to --deployable--.

In Column 10, Line 59, change "vasodialators, sirolamus," to --vasodilators, sirolimus,--.

In Column 21, Line 2, change "state." to --state,--.

In Column 33, Line 49, change "an" in line 4 of claim 1 to --a--.

In Column 33, Line 61, change "artery" in line 16 of claim 1 to --cerebral blood vessel--.

In Column 34, Line 12, change "artery" in line 3 of claim 3 to --cerebral blood vessel--.

Signed and Sealed this
Twenty-sixth Day of June, 2012

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office